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GOVERNMENT OF THE REPUBLIC OF SERBIA
MINISTRY OF ECONOMY

STRATEGY

FOR THE IMPROVEMENT OF QUALITY INFRASTRUCTURE IN THE REPUBLIC OF SERBIA

FOR THE PERIOD 2015-2020

Contents

Abbreviations and Terms

EU	European Union
WTO	World Trade Organization
WTO/TBT	World Trade Organization Agreement on Technical Barriers to Trade
QI	Quality Infrastructure
ISS	Institute for Standardization of Serbia
ATS	Accreditation Body of Serbia
DMDM	Directorate for Measures and Precious Metals
CEFTA	Central European Free Trade Agreement
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
ETSI	European Telecommunications Standards Institute
EA	European Accreditation
EURAMET	The European Association of National Metrology Institutes
WELMEC	European cooperation in legal metrology
GIZ ACCESS	Bilateral support programme of the German government to the Quality Infrastructure sector
CAB	Conformity Assessment Body
SAA	Stabilization and Association Agreement
NPAA	National Program for Adoption of Acquis of EU 2013-2016
Decision 768/2008/EC	Decision of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
Regulation 765/2008/EC	Regulation of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
Regulation 764/2008/EC	Regulation of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC
Harmonized Standard	A harmonized standard is a European standard elaborated on the basis of a request from the European Commission to a recognized European Standards Organization (CEN, CENELEC or ETSI) published on the list of harmonized standards in the official Journal of the European Union and the compliance with which provides a presumption of conformity with the corresponding requirements of the legislation in which they are referenced.
National technical regulation	Serbian autochthonous technical regulation for groups of products that are not the subject of harmonization on the EU level (non-harmonized area)

INTRODUCTION

Full integration of Serbian economy into the single EU market - consisting today of 28 member states- is one of the strategic goals of the Republic of Serbia. Being a part of the single market implies open access to a market of over 500 million consumers, and creation of favorable conditions for complete introduction of Serbian economy into the international production processes.

Serbia's path towards EU accession and full-fledged membership in WTO implies, among many other reform processes, preparations for full adhering to the requirements of the competitive common market.

In the process of joining the EU and WTO, candidate states shall adopt measures to ensure free movement of goods, taking care that only products not threatening human safety and health, environment, property and other public interests are being placed on the market.

This requires strong commitment to product safety and quality, as well as implementation of one of the basic principles of the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement) - ensuring that technical regulations and standards, and the relevant conformity assessment procedures, do not create unnecessary obstacles to international trade.

One of the important preconditions to achieve this goal is the establishment of efficient national quality infrastructure. Passing of the National Quality Infrastructure Improvement Strategy in the Republic of Serbia for the period 2015- 2020 will lay down next steps for a dynamic and comprehensive development of metrology, standardization, accreditation and conformity assessment, as elements of quality infrastructure. In that context, the Strategy is setting development priorities for the forthcoming period, in accordance with the needs of Serbian industry and current development trends, both in Europe and worldwide.

Generally speaking, national quality infrastructure supports development of all industrial branches given that it represents the basis for safety and quality of all products, in all phases, from design, through production, to their placing on the market. To achieve a balanced development of quality infrastructure aligned with the needs of Serbian industry, i.e. provide adequate services to the industry, it is necessary to establish a long term strategic framework for further QI development.

This document will set forth strategic orientation of the QI development in the Republic of Serbia, based on the analysis of the current situation in this area and plans for the industrial sector development, mainly in the area of non-alimentary industrial products.

In the process of the QI system improvement and modernization in the Republic of Serbia, the Ministry responsible for economic affairs (hereinafter: the Ministry), being a public authority in charge of the development policy in the areas of metrology, standardization, accreditation and conformity assessment, shall undertake activities aimed at creating the normative and institutional basis for the development of these areas in accordance with European legislation and practice.

By completing the improved system of quality infrastructure, the Republic of Serbia will be a few important steps closer to Europe and its values in the EU integration process, which will have a positive impact on:

- Serbian businesses, which will produce, import and export products without unnecessary technical barriers,
- Customers who will be guaranteed to have safe products,
- Government authorities, which will be able in a more simple and efficient way to conduct supervision over the implementation of technical regulations.

By reaching these goals, the Republic of Serbia will be in a position to become an active participant on the European and global markets.

1. METHODOLOGY

In the last five years intensive legislative activities regarding harmonization with the EU legislation and institutional capacity building in the area of quality infrastructure were conducted. In line with industry needs and EU integration requirements it is necessary to establish a long-term policy and action strategy in this area in order to achieve full operability of the established system.

The Ministry (of Economy), as the authority in charge of the elaboration of the development policy in the areas of metrology, standardization, accreditation and conformity assessment and coordination of the competent public authorities responsible for drafting and implementing technical regulations (Law on Ministries, Official Gazette of RS, No 72/12), has elaborated the Quality Infrastructure Development Strategy for the period 2015- 2020.

Principles used in the development of this Strategy were as follows: harmonization with the relevant national strategies and international rules and good practices, cooperation with the competent institutions, companies and their associations, as well as balance between the mid-term and long-term development goals.

Development priorities in the QI domain identified in this Strategy have been harmonized with the relevant strategic priorities defined in the framework of: Industrial Development Strategy (2011-2020), Fiscal Strategy for 2013 with projections for 2014 and 2015, Market Surveillance Strategy, National Strategy for the EU-accession and National Program for Integration of the Republic of Serbia to the EU –NPI (2014-2018), Stabilization and Accession Agreement (Art. 77 and Articles 20 and 21) and CEFTA Free Trade Agreement in Southeast Europe.

An important instrument for enhancing competitiveness of Serbian industry recognized in the **Industrial Development Strategy and Policy of the Republic of Serbia for the period 2011-2020** is reflected in the harmonization of technical regulations and standards with international, i.e. European rules, and strengthening of relevant institutions as an important prerequisite in creating business environment that would enable export of Serbian products to foreign, primarily EU, markets. In order to achieve a balanced development of quality infrastructure in accordance with the Serbian industry needs, i.e. provide adequate services to the industry, it is necessary to establish a long term strategic framework for further QI development as one of the elements underlying implementation of this Strategy.

Fiscal Strategy for 2013 with projections for 2014 and 2015, in its part referring to structural reforms aimed at intensifying business activities, has identified, inter alia, the need for improvement of national quality infrastructure, including: full harmonization of standards that are essential for the competitiveness of industry and their translation into Serbian; full participation of the Serbian Institute for Standardization in the regional and international standardization activities; full integration of Serbia in the international measurement system; capacity building of the national metrology institution to directly respond to the private sector needs; improved testing and

certification, establishment of testing laboratories and environmental protection, as well as conformity assessment bodies for the product certification; strengthening the national accreditation body in assessing conformity assessment bodies' qualifications to render services of conformity assessment in the areas of testing, inspection, and the certification of products, systems and personnel.

Market Surveillance Strategy emphasizes the importance of the improvement of the legal framework for the safety of non-food products as well as the role of Market Surveillance in enforcement of technical regulation aiming at health and safety protection, environmental protection and other aspects of public interests. Although market surveillance is significant for the efficiency of the entire QI system, due to the existence of the current Market Surveillance Strategy, this strategy does not deal with all sub-disciplines of market surveillance, rather only with measures and activities of market surveillance for the purpose of ensuring conformity of products with safety, technical and other requirements stipulated by technical regulation.

National Strategy for the EU accession from 2005 has identified, inter alia, the need for harmonization of national technical regulations with the EU directives, i.e. their transposition, as well as harmonization with the rules of the World Trade Organization.

Based on **The Stabilization and Association Agreement (SAA, Art. 77)** Serbia is obliged to undertake necessary measures in order to gradually harmonize technical regulations with EU as well as European Standardization, Metrology, Accreditation and Conformity Assessment Procedures. Foreseen joint measures within a.m. agreement are harmonization of technical regulations and promotion of implementation of European standards and Conformity Assessment methods. The EU has committed itself to support QI development in Serbia and Serbia's active participation in the work of relevant European organizations in the field of Standardization, Accreditation and Metrology (e.g. CEN, CENELEC, ETSI, EA, WELMEC, EURAMET, etc.). At the same time Serbia and EU have obliged themselves, when all necessary preconditions are fulfilled, to sign appropriate agreements on Conformity Assessment and mutual acceptance of certain industrial products. Also, with the Article 20 and 21 of the SAA, Serbia and the EU committed themselves that during the import of industrial products originating in the EU or Serbia will abolish all quantitative restrictions and measures having equivalent effect.

National Program for Adoption of Acquis (NPAA, 2014-2018) goes more in detail regarding fulfillment of SAA. In the chapter regarding the ability of taking over obligations arising from the membership in the field of Free Movement of Goods, a precise plan for harmonization of legislative system of Serbia with EU-rules and full implementation of Technical Legislation is presented.

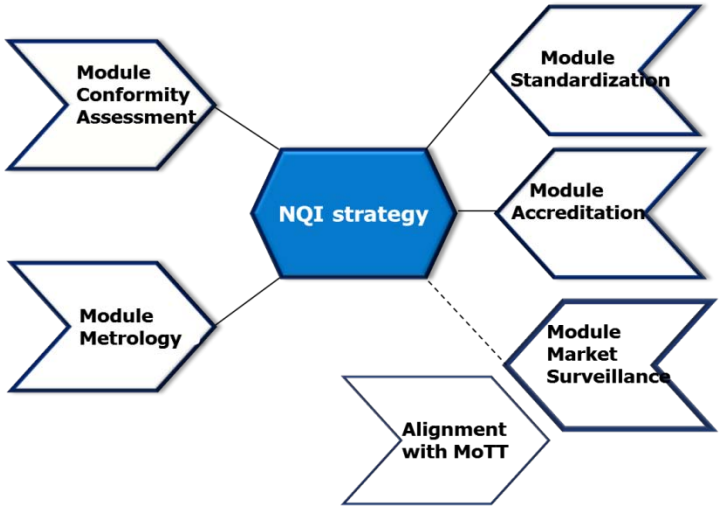
Free Trade Agreement for South East Europe (CEFTA) that Serbia signed in 2006 focuses on elimination of Technical barriers to Trade, **primarily** through harmonization of Technical Regulations and standards. The final goal of these measures is to ease trade of products and services in the CEFTA region by elimination of non-tariff barriers through mutual recognition of Conformity Certificates respectively.

Besides the above-mentioned strategic documents, in the process of elaboration of the Strategy, analysis and recommendations of other publications such as Foreign Investors Council´s "White Book" from 2012 – "Proposals for Improvement of the Business Environment in Serbia" were used.

For the elaboration of this Strategy, the Ministry formed a multidisciplinary team, consisting of national and international experts and representatives of stakeholders, primarily key QI institutions. Relevant expert assistance in the Strategy elaboration was ensured through technical support program of the German Organization for International Cooperation (GIZ ACCESS).

An analytical modular approach was used in order to identify the state of affairs and requirements in the QI area, starting from the industry needs for QI services to formulation of strategic development orientation (Graph1), accompanied by the development of a detailed respective methodology.

Graph1: Modular approach to the Strategy development



During the first phase of the Strategy development 4 analyses were conducted:

- Analysis of the Conformity Assessment System in Serbia
- Analysis of the industry demand for QI services
- Analysis of institutional capacities (ATS, ISS and DMDM) in the QI area
- Analysis of functionality of the new legislative framework.

Ministry of Economy has prepared a questionnaire and conducted interviews with the economic operators identified as key industry representatives in the relevant sectors.

Conducted analyses included 30 Conformity Assessment Bodies (CABs) and 40 economic operators, mostly companies, to collect information on actual requirements and obstacles regarding the implementation of technical regulations. Economic operators interviewed came from sectors covered by the European directives on machine safety, lifts, low voltage equipment, electromagnetic compatibility, personal protective equipment, pressure equipment and construction products.[1] The feedback of economic operators was very positive and expressed their appreciation for being included in the process of elaboration of the long-term strategy document in its earliest phase. Thanks to this approach collected information was of high quality.

[1] Research from 2011, conducted by SIEPA showed that foreign investors are very interested in investing in following sectors (in order of significance): automotive industry, electronic and electro industry, textile industry, construction industry, machine building industry, which is more than 60% (*Automotive Profile Serbia* and *Doing Business in Serbia)*

Besides these analyses and in order to identify shotcomings of the Serbian national quality infrastructure system in comparison with developed EU countries and regarding future development trends, a benchmarking was perormed with the quality infrastructure systems in Germany and Slovenia.

Dynamics and instruments for the operational implementation of the Strategy and achievement of the defined goals will be elaborated in detail through action plans and mechanisms for the monitoring of the Strategy implementation.

2. ELEMENTS AND RELEVANCE OF QUALITY INFRASTRUCTURE SYSTEM

2.1. Elements of the Quality Infrastructure system

Quality infrastructure (QI) encompasses the following elements: metrology (legal, scientific and industrial), standardization, accreditation and conformity assessment.

Quality infrastructure system implies the existence of at least three institutions: National Standards Body, National Metrology Institute and National Accreditation Body, and numerous conformity assessment bodies (CABs) – legal entities and economic operators that are mainly privately owned. National institutions of the QI system strive towards full membership in the corresponding European and international institutions that promote the exchange of experiences and practices and conformity at international level.

Metrology is tasked with ensuring reliability and accuracy of results of measurements traceable to the international system of units (SI). That can be achieved with use of accurate measuring tools compliant with requirements established on the international level that ensure measurement results traceable to the national standard and from there to the international standard. Metrological activities are greatly significant for ensuring quality of industrial processes, reliability of laboratory research, safeguarding the health and safety of people, safety of traffic and property, protection of consumers in purchasing relations as well as control of protection of living and working environment.

Metrology encompasses fundamental, legal and industrial metrology.

- Fundamental metrology refers to establishment, development and preservation of standards with scientific methods (e.g. Establishing a meter, as a unit of measurement of length, with a laser);
- Legal metrology is the part of metrology referring to legally stipulated activities relating to units of measurement, measuring tools and measuring methods used in the function of goods and services turnover, protection of health and general safety, protection of environment, control and safety of traffic and other. It encompasses the following activities: assessment of conformity of measuring tools with stipulated requirements; metrological surveillance (as a specific type of market supervision); examination of previously packed products; supervision of work of authorized bodies and coordination of holders of national standards.
- Industrial metrology ensures accuracy of measuring tools used in production processes and examination procedures (e.g. Devices measuring hardness of materials used in production processes);

National metrological institute holds the primary role for ensuring that metrological system works.

Standardization is a set of coordinated activities on elaboration and adoption of standards and related documents. Standards and related documents are adopted by international organizations or by national institutes for standardization. Through the voluntary participation of all interested parties, standards are defined by consensus, determining rules, requirements, characteristics, instructions, recommendations or guidelines for activities or their results with the aim of achieving the optimal level of order in a specific area in relation to the current or potential problems.

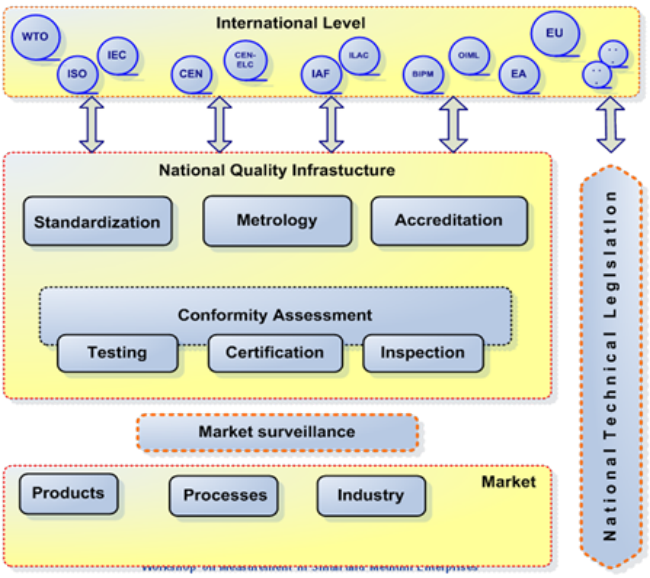
The role of standards in ensuring conformity with the essential requirements of relevant European technical regulations is very important in the process of harmonization of national legislation with EU technical regulations. Therefore, standardization contributes considerably to development and improvement of production and marketing of products, implementation of activities, i.e. rendering services, improving quality of products, processes and services, their standardization, compatibility and interchangeability, improving protection of life, health and safety of people and property, environmental protection, as well as promoting international trade by preventing and removing unnecessary technical barriers.

Accreditation is a procedure of determining the competence of conformity assessment bodies to perform conformity assessment activities. That is a procedure in which national accreditation body confirms whether the conformity assessment body conforms to the requirements of the relevant national, international and European standards, and, when applicable, all additional requirements defined for a particular area. Through this procedure, competence of the conformity assessment body to carry out testing, calibration, inspection and certification of products, management systems and persons, and other conformity assessment activities is formally recognized. All this contributes to greater trust in the results of conformity assessment and elimination of unnecessary technical barriers to trade, as well as strengthening the competitiveness of the national industry on the international market.

Conformity assessment is a set of different activities (testing, certification of products, management systems, and persons, calibration, inspection, etc.) established in order to verify and determine if a process, product or service has met the respective requirements laid down in regulations, standards or technical specifications. Conformity assessment is a commercial activity and may be mandatory in cases where the product has to meet the essential requirements of technical regulations, or can be voluntary, when the product is checked for compliance with the requirements of a standard. Although conformity assessment represents a cost for producers who strive to minimize it, all participants in the market can benefit from CA, from the manufacturer to the end user of the product or service. This strengthens confidence in the safety and quality of products and services.

Correlation between the basic elements of QI in the national QI system can best be seen in the example of preparing a product to be placed on the market. The product should be designed and manufactured according to defined (recommended, prescribed) requirements, standards or technical specifications (national technical legislation, standards established by the national standardization institution or particular technical solutions of the manufacturer) and tested, i.e. certified by the competent conformity assessment body (testing laboratory and certification body) – whose competence is usually confirmed with accreditation. In the process of production and testing, measurement instruments that are used should be calibrated in order to provide reliable measuring results, and their accuracy proven by traceability to international measurement standards (national metrology institute).

GraphNr. 2: Role of Quality Infrastructure and correlation of between the elements



2.2. Relevance of the modern quality infrastructure system

The basic premise of modern industrial production and international trade in goods is conformity of products and production processes with the requirements of quality and safety. To achieve this goal, each country needs to develop its own quality infrastructure system, which will serve as a framework for enhancing safety of industrial products on the market and protection of other public interests.

An effective and efficient national quality infrastructure system is a prerequisite for:

a) Placing safe and quality products on the market and ensuring high level of consumers' rights protection;
b) Free movement of goods and removing technical barriers to trade;
c) Easier access of national producers to international markets;
d) Achieving higher level of industry innovations and competitiveness;
e) Sustainable economic development and environmental protection.

To facilitate consumers' access to safe and quality products, a product has to conform to specified requirements, standards and other technical specifications. It means that the product has been designed, produced and inspected using the national QI system and that its conformity has been verified.

Free movement of goods on the international market, without unnecessary technical barriers, is achieved through implementation of the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT), and through other bilateral and multilateral agreements on mutual acceptance of industrial products and conformity assessment. In this way, differences in national

regulations and the need for multiple inspections, when placing a product on the market of another country, are being eliminated.

Free movement of goods on the EU market, without unnecessary technical barriers is achieved through harmonization of regulations, standards, and conformity assessment procedures for products and market surveillance on European level, including the application of mutual recognition in non-harmonized area. During the EU integration process, Serbia is intensively working on harmonization of the national technical legislation and national standards with European legislation and standards in line with SAA and NPAA.

EU-oriented Serbian exporters are already able to fulfill requirements of the EU regulations and standards directly. Nevertheless, it would be much easier for economic operators if these regulations and standards were also in place in the domestic market. Through harmonization of technical legislation and standards producers would be in position to place their products on both domestic and foreign markets under the same conditions and increase their competitiveness. Implementation of modern standards in all phases of the industrial production process, steers producers to continually adapt and upgrade their technical and technological capacities, thus stimulating their innovativeness and competitiveness.

A modern and efficient QI contributes to strengthening of production, protection of public interests, and supports competitive production which represents the core of sustainable economic development.

2.3. QI in Europe: State of the art and major development trends

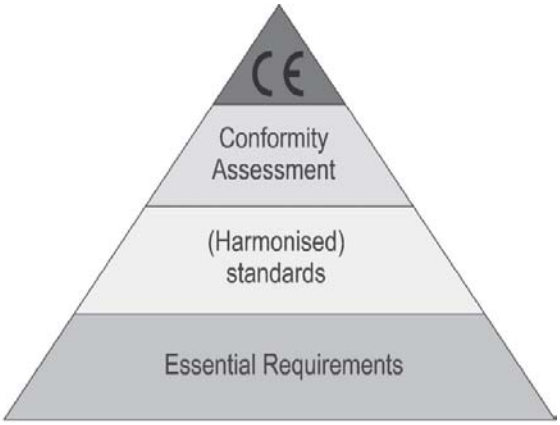
The Single Market is one of the great achievements of the European Union. Basic principles of this Market - free movement of goods, services, capitals and labor – provide foundation for prosperity of the Member States. For the purpose of practical implementation of these principles, harmonization of legislation in all these areas was conducted over a long period of time.

In order to ensure the free movement of goods and to develop the unique internal market, it was not enough just to remove tariff barriers between member states but also to harmonize technical regulations for variety of products, and they were mutually incompatible due to different traditions and practices in different European countries. Until 1985, technical legislation for industrial products of the Member States was harmonized through transposition of the so called “Old Approach Directives” which contain detailed technical specifications with references to standards which sometimes renders these standards mandatory. The process of adoption of the directives was very long and complex because the consensus of all Member Countries was required. Nevertheless, “Old Approach” has certain advantages and that is why it exists even today in the most sensitive groups of products (e.g. medicines, chemical products, motor vehicles). Due to the potential danger that such products could pose, Member States had an interest to keep the competence in assessing conformity.

As the “old Approach” became more complex, a need for new legal techniques arose. Therefore, European Council adopted the Resolution on “New Approach” in 1985. By adopting a new Resolution, a new regulatory technique was introduced for different sectors such as: electrical/electronic products, pressure equipment, lifts, machinery, toys, construction products,

personal protective equipment, medical devices, etc. In this way legal harmonization was facilitated, and some novelties were introduced into the EU QI system. “New Approach” Directives regulate only essential requirements for products, and technical details are included in harmonized standards whose application provides a presumption of conformity of products with their essential requirements.

GraphNr. 3: Model of the New Approach in the field of Technical Regulation



Yet, some aims and provision of a New Approach were to some extent differently interpreted in practice, so a review of selected aspects of the new Approach became necessary:

- improvement of the exchange of information and experience among notified bodies;
- harmonization of the requirements for notified bodies as well as of the notification procedures;
- improvement of administrative cooperation as regards market surveillance;
- acceleration of the safeguard clause procedure (f.e. withdrawal of the product from the market that is harmonized with technical regulations and still can endanger the public interest);
- strengthening the credibility of the CE marking (recognizing that the CE mark is no longer an instrument for manufacturers and market surveillance authorities only, but for the consumers as well).

Reasons and needs for the revision of a “New Approach” brought up a so called “**New Package of measures for enhancing trade of products”. (New Legislative Framework – NLF)** included:

- **Decision No 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on common framework for the marketing of products, and repealing Council Decision 93/465 EEC;
- **Regulation (EC) No 765/2008** of the European parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC)No 339/93;

- **Regulation (EC) No 764/2008** of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

Directives of the "Old" and "New Approach" regulate requirements regarding product safety on the Single Market (harmonized area). In the cases where the regulations and standards for some product groups are not harmonized on the whole Single Market (non-harmonized area), every member country can apply its national technical regulation and national standards.

Graph Nr. 4: Balance between harmonized and non-harmonized area and their connection with product safety

National non-harmonized technical regulations are always a potential barrier to trade. Therefore, provision of information about it towards WTO and EU (notification) is of a significant importance and can have a preventive impact.

In order to avoid, for non-harmonized sectors, that products that are lawfully marketed in one Member State, are rejected by other Member States on the sole grounds of different national rules, Regulation 764/2008/EEC was introduced. This Regulation deals with procedures which are relevant to the implementation of the "principles of the mutual recognition" for a broad spectrum of products from the non-harmonized field such as furniture, bicycles, precious metals products etc.

One of the novelties deriving from the Regulation is establishment of the "contact points for products" as an important instrument for strengthening of the internal market. In every country, contact points for products provide information to the economic operators about technical regulations applicable in the country. They also provide detailed information on products for which mutual recognition regulation as well as national technical regulation is applicable. This part of the regulation must not be adopted before EU membership. Nevertheless, candidate countries have to be ready for its full implementation.

European trends in the field of Metrology

The Measuring Instruments Directive (MID) and the Non-Automatic Weighing Instruments Directive (NAWID) form the basis in the field of legal metrology in the European Union. According to the Decision EC 768/2008 both directives have been slightly modified in 2014. Measuring instruments, which are not harmonized on a European level can be regulated at a national level

keeping in mind Regulation 764/2008/EC and requirements of the Directive 98/34/EC concerning the reporting of drafts of technical regulation (notification) to European Commission.

The European Directive on Pre-packages regulates the control of pre-packed products by surveillance of manufacturers and packers of pre-packages as well as control of pre-packages having been put on the market. This Directive will be kept unchanged in the coming years.

According to Regulation 765/2008/EC for Accreditation and Market Surveillance every member state has to secure sufficient market surveillance activities in general, which also covers measuring instruments and pre-packages. Due to the complexity of controlling measuring instruments and pre-packages, only authorities having the relevant metrological competence can perform this task.

With the aim of uniform and harmonized application of mentioned directives, member states of the EU, via competent authorities for legal metrology and in cooperation with the European organization for legal metrology (WELMEC), are working to develop guides for their implementation.

In the areas of industrial and scientific metrology the European National Metrology Institutes have already started an ongoing process of coordinating research activities to increase efficiency in metrological research, through research programs, such as: MERA, iMERA, iMERA+ and EMRP. According to the great success of these programs in 2014, the new follow-up program called EMPIR was launched. Active participation in this program will be essential to the further development of national measurement standards and associated calibration and measurement capabilities, especially in the fields of innovation in industry, energy, health and environmental protection.

In addition this program covers also capacity building and pre-normative research in the field of legal metrology.

European trends in the field of Standardization

Publication of EU Regulation No 1025/2012 of the European Parliament and of the Council on European standardization significantly influenced current and future state of standardization in Europe.

The purpose of this Regulation is modernization and improvement of processes of adoption of European standards in order to speed up this process, with a more active involvement of all interested parties, and ensure wider application of said standards in practice.

The Regulation deals with a range of topics that impact both on the European standardization organizations and national standards bodies, including the following:

- Facilitating of effective access to standards (f.e. by removing of language barriers) and enhancing the participation of SMEs in the standard-setting process;
- Ensuring a more efficient cooperation between European organizations for standardization, national bodies for standardization and the European Commission;
- Ensuring a more direct involvement of all interested parties in European standardization;
- Establishing European standards for services as a support to the EU legislature;
- Improving and accelerating the European standard-setting process on the European level through increase of transparency of the procedure itself and consulting interested parties;
- Identification of technical specifications resulting from work of professionals for and from the information and communication technologies sector, and that would be used in European standardization or legislature;
- Sustainable financial models for the European standardization.

The new Regulation clearly strives at making participation in European standardization work more direct and immediate for the largest possible scope of stakeholders, whilst giving maximum

attention to more vulnerable stakeholders (consumers, economic operators that have scarce resources to be invested in standardization, such as SMEs, etc).

The role of standardization in support of legislation has once more been confirmed, and the regulation reflects the intention of the Commission to extend the New Approach and its mechanisms (essential requirements in harmonized legislation, indicative reference to harmonized standards) to the services sector. Against this background it is not surprising that the regulation sets stringent requirements for fully transparent and effective cooperation between public authorities (including market surveillance authorities) and national standards bodies.

A number of the tasks and expectations that national standards bodies are faced with in complying with the Regulation were already foreshadowed by the publication of CEN-CENELEC Guide 20: Guide on Membership Criteria of CEN and CENELEC, published in 2011. The criteria are based on a „voluntary approach of self-imposed requirements, to be fulfilled by all national CEN and CENELEC Members at all times. " National standards bodies are thus encouraged to invest in their continuous improvement and the exchange of good practice along the lines stipulated by Regulation No 1025/2012.

European trends in the field of Accreditation

Europe has set a basis in the field of accreditation by establishing the Regulation (EC) No 765/2008 which for the first time introduces a legal framework for accreditation. The regulation sets out the requirements for accreditation and market surveillance relating to the marketing of products. One main purpose for introducing the Regulation (EC) No 765/2008 was to enhance trust in conformity assessment results by strengthening accreditation as the last level of control in the conformity assessment system.

The European Cooperation for Accreditation (EA) is taking over a major role as the new European accreditation infrastructure. In June 2010, the Commission and EA signed a framework partnership agreement for the period of 2010-2014 allowing financial support for EA in fulfilling its tasks outlined in the Regulation (EC) No 765/2008.

The Regulation (EC) No 765/2008 promotes accreditation as the best way for determination of competences of CABs. Although accreditation is not a formal requirement for registration of notified CABs to EU Commission, accreditation is an important and most frequently used instrument for evaluating the competence and integrity of the conformity assessment bodies to be notified.

The relevant national authorities of a member state consider accreditation when dealing with applications and thereby reduce the differences in the criteria applied for notification.

The actual use of accreditation for notification purposes differs across Member States and across sectors. At the end of 2009, before Regulation (EC) No 765/2008 came into force, about 50% of the notifications were based on accreditation (1118 out of 2249). In two and a half years the percentage of notifications based on accreditation rose to about 70 % (2196 out of 3106) by June 2012[2]. This trend gives evidence that accreditation has become the most used tool for the evaluation of conformity assessment bodies for notification purposes. As it can be assumed that this trend will continue in future, so emphasis should be made to apply this principle more broadly in the implementation of technical regulation also in candidate countries.

[2] European Commission (2013) (Ed.): COM(2013) 77 final - Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No339/93, Brussels.

European trends in the field of Conformity Assessment

Besides the novelties regarding the rule of Accreditation in the Notification Process, new legislative framework (NLF) and especially decision No 768/2008/EC and Regulation No 765/2008/EC became a basis for the revision of New Approach directives.

European rules in the field of conformity assessment are baised on the choice of Conformity Assessment module which depends on: a) type and complexity of a product; b) nature of the product risk; c) economic structure of the specific sector; d) type and relevance of manufacturing; e) principle of proportionality.

Both Decision and Regulation describe, inter alia, criteria for Designation and Notification of Conformity Assessment Bodies. NANDO (New Approach Notified and Designated Organizations) database is an electronic database of the European Commission containing data about registered bodies for evaluation of conformity from certain member states. This database was improved by the inclusion of new characteristics that enable preliminary and final notification in order to satisfy the requirements of the new legislative framework regarding obtaining of the notified body status.

3. ANALYS OF THE QI SITUATION IN SERBIA

3.1. Legislative framework

3.1.1. Horizontal legal framework of QI

Legal framework for quality infrastructure in the Republic of Serbia was established by passing four framework laws in the areas of technical requirements for products and conformity assessment, standardization, metrology, accreditation, as well as passing all by-laws for their implementation.

Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of RS, No.36/09) represents a basic legal framework for transposition of European technical legislation into the domestic legal system, unless stipulation of technical requirements for products has been prescribed by specific laws At the same time, it also provides the legal framework for the stipulation of national technical regulations for products not comprised by the harmonized regulations at the EU level.

Several bylaws were passed in order to implement this law, which regulate: ways of implementation of evaluation of conformity; ways of appointment and authorization of CABs; ways of recognizing foreign documents and marks of conformity; procedure for reporting and informing referring to technical regulations, conformity assessment and standards; ways of placing marks of conformity on products, as well as use of marks of conformity; content and way of keeping registers referring to technical regulations and contents of forms used to publish a list of Serbian standards referred to in the technical regulation.

Law on Standardization (Official Gazette of RS, No. 36/09) asserts establishing Serbian standards based on European and international standards, as well as making the application of standards voluntary. This Law regulates general standardization covering the broadest range of users and not the sector standards applied in specific areas (rail, air and river traffic, defense, etc).

Likewise, it provides conditions for a more rapid and efficient adoption of the EU standards, and fulfillment of requirements for full membership in European organizations for standardization.
Based on this law the Decision on the Amendments to the Act on the Establishment of the Institute for Standardization of Serbia (Official Gazette of RS, No. 88/09), which regulates in detail establishment, organization and work of the institute.

Law on Metrology (Official Gazette of RS, No. 30/10) represents a basic legal framework for organizing the metrology system in the Republic of Serbia, which means organizing metrology tasks, legal measuring units, standards of the Republic of Serbia, putting in circulation, use and legal inspection of measuring instruments. During the making of this law, documents of the International Organization of Legal Metrology – OIML D1 and OIML D9, and EU regulatory rules on metrology, were taken into account.

For the enforcement of this law, 15 by-laws were adopted, which inter alia describe more in detail the following: measuring instruments subject to metrology market surveillance, methods and preconditions for authorization and designation of conformity assessment bodies ("DI") and verification of measuring instruments respectively, conducting metrology market surveillance, recognition of foreign certificates, marks and signs of conformity and other issues related to metrology system. Additionally, the law provides a legal basis for the adoption of European directives in the field of Metrology, allowing for the transposition of the "MID" regulating 10 types of measuring instruments, "NAWI" dealing with non-automatic weighing instruments, as well as the directive on pre-packaged products and units of measurement). Furthermore based on this law requirements for measurement devices in the non-regulated area are defined (national regulations).

Law on Accreditation (Official Gazette of RS, No. 73/10) comprehensively regulates the accreditation system, which in addition to national accreditation body contains accredited conformity assessment bodies, as well as rules and procedures for accreditation, establishing competencies of conformity assessment bodies (testing, calibration, inspection and certification of products, management systems and persons). Based on this law, the Decision on changes and amendments of the founding document of the Accreditation Body of Serbia (Official Gazette RS Nr. 14/11 which regulates establishment, organization and work of this body, was adopted.

All four laws have adopted solutions contained in the New Legislative Framework NLF, so-called „*new goods' package*".

3.1.2. Horizontal legal framework amending laws

Very important laws that encompass horizontal legal framework of QI in the Republic of Serbia are Law on General Safety of Products (Official gazette of RS Nr. 41/09) and Law on Market Surveillance (Official gazette of RS Nr. 92/11).

Law on General Safety of Products is a legal basis for ensuring safety of all products especially of those that are not covered by technical regulations determining significant requirements regarding product safety. This law took over the principles and most important requirements of the EU Directive on General Safety of Products (2001/95/EC), and Directive on the approximation of the laws of the Member States concerning products which, appearing to be other than they are (87/357/EEC), and promotes the basic principle that all products placed on the market have to be safe. Law on General Safety of Products defines, besides general precondition for safety, criteria for conformity assessment according to general product safety requirements, as well as notification on risks that this product can cause regarding health and safety of persons. One of the most important novelties, introduced into our legal system by this law is setting up the system for fast exchange of information on dangerous products, i.e. products that pose a significant risk to

health and safety of consumers and professional users of these products. System for fast exchange of information on dangerous products (NEPRO) aims to create an integrated system approach of all relevant authorities of market surveillance in gathering and dissemination of information on dangerous products and to further develop regional and international cooperation in the area, including the accession of the Republic of Serbia to the RAPEX system and notifying the European Commission, once Serbia becomes a full EU member.

Law on market surveillance systemically regulates: general rules of market surveillance, market surveillance authorities and their scope of work, cooperation, the exchange of information and communication between the market surveillance authorities and customs authorities, and coordination between the market surveillance authorities and monitoring of the market surveillance activities. According this law, market surveillance, as a set of activities implemented and measures taken by market surveillance market, intended to ensure product compliance with safety, technical, and other requirements set out in suitable regulations. That ensures that the products placed on the market of the Republic of Serbia do not compromise human health and safety or other aspects of public interests. Market surveillance over the implementation of technical regulation represents an important link in the system of quality infrastructure. By introducing the Law on market surveillance, the area of market surveillance is aligned with Regulation Nr. 765/2008/EEC.

3.1.3. Technical Regulations in the Republic of Serbia

Technical regulations define technical, safety and other requirements and preconditions for products that are placed on the market and put into use, as well as conformity assessment methods regarding prescribed requirements. Fulfillment of technical regulations requirements is proven with the application of procedures for assessment of conformity. Therefore, they are one of the more significant elements of the QI system.

Together with the horizontal legislative framework, technical regulation builds Serbian technical legislation. Nowadays, there are two basic groups of technical regulation: technical regulation for adoption of EU technical regulation, especially Old and New Approach Directives, and national (indigenous) technical regulation.

Enforcement of the National Program for Adoption of Acquis of EU (NPAA) that puts forward the plan for adoption of EU technical regulation is in progress. Nevertheless, not all directives are harmonized with the same speed, so that some ministries have significant delays in plan realization.

Table Nr. 1: Number of valid technical regulation and ministries in charge of their adoption

(Register of technical regulation www.tehnis.privreda.gov.rs, May 2014)

Competent institutions and areas	Number of technical regulation
Ministry of Economy - technical requirements for industrial products and processes Directorate for Measures and Precious Metals - technical requirements for measuring instruments and pre-packaged products	 67 139
-Ministry of Mining and Energy - technical requirements in the field of: oil, gas, electrical energy, mining and geology	 60

- technical requirements in the field of energy	22
Ministry of Agriculture and Environmental Protection - technical requirements for foodstuffs and animal feed - technical requirements in the field of forestry - technical requirements in the field environmental protection	 58 35
Ministry of Health - technical requirements on quality, sampling methods and analysis of certain foodstuffs - technical requirements for medical devices	35
Ministry of Construction, Transport and Infrastructure - technical requirements in the field of Construction - technical requirements for means of transport and traffic infrastructure in the fields of: road, rail, water and air traffic Civil Aviation Directorate - technical requirements in the field of aviation	 42 181 4
Ministry of Trade, Tourism and Telecommunications - technical requirements for products and systems in the field of telecommunication	15
Ministry of Interior - technical requirements in the field of protection against fire and explosions - technical requirements for roadworthiness test of vehicles	38
Ministry of Defense - technical requirements for shelters and dual-purpose facilities	6
Serbian Radiation Protection and Nuclear Safety Agency	1
Total	703

It is of crucial importance that all national technical regulations be registered and a plan for their systemic management put into place. A significant step in this direction was taken in 2009, when an Action plan for drafting of technical regulations with measures for their application was implemented. Implementation of the Action plan has contributed to a clear delineation of jurisdiction of bearers of regulations, repeal of outdated and contradictory technical regulation, establishment of a registry of all valid technical regulation and availability of information on technical regulation in one spot through internet portal TEHNIS. During the implementation of the Action plan, the conclusion was reached that it was necessary to further strengthen the capacity of the body of the public administration competent for preparation, bearing, i.e. implementation of technical regulation, which has been only partially achieved by 2013 and 2014.

According to the rules of the WTO/TBT agreement, analogous to the rules that apply to standards, technical regulations should be periodically reviewed, e.g. every five years. In practice, that means competent institutions should establish a system of continuous reviews of all valid technical regulations during which the effect of implementation of regulation will be analyzed and assessed whether they are actually implemented and whether their implementation is subject to the market surveillance. It should also be checked whether there are designated/ accredited bodies for conformity assessment of products that are subject to those regulations or are these regulations technically outdated and because of that no longer ”de facto” applied by the economy, and need to be changed or repealed.

Notification of technical regulations in their drafting phase is also one of the obligations for members of WTO and EU, and it is performed with the aim of identifying and removing potential unnecessary technical barriers to trade. For the purposes of notification of valid technical regulation in the preparation of WTO and EU, the Republic of Serbia has already passed a corresponding legal

act – a Regulation that adopts Directive 98/34/EC, which governs registration of technical regulations and Serbian standards. As this directive was changed in 2012 by a Regulation on Standardization in EU No 1025/2012, it will be necessary to revise this legal act. However, implementation of the Regulation was not sufficiently efficient so far because the ministries did not entirely fulfill their obligation of notification about regulations being drafted. This is why it is necessary to renew the campaign on the importance of the notification procedure about technical regulations not only for the state administration, but also for raising awareness of the economic entities and their associations on the role they have concerning remarks/ comments, both on proposed draft versions of Serbian technical regulations and notified foreign technical regulations.

Aside from the harmonization of Serbian technical legislation with that of the EU, it is necessary to perform the analysis of the effects of application of indigenous national technical regulations because of the appropriate changes i.e. repealing outdated and mutually conflicting regulations. In order to achieve full transparency of the Serbian technical legislation, after the implementation of the harmonization procedure and removal of outdated and mutually conflicting regulations from the legal system, it is necessary to reexamine all other national technical regulation in terms of full conformity with articles 34-36 of the Treaty on the Functioning of the EU (TFEU). This reexamination will be done through enactment and application of the Action plan referring to the national technical rules and administrative measures for trading with products in a non-harmonized area. Action plan should define the role and obligations of competent ministries to perform an analysis of these rules and measures in accordance with the results of the analysis, proposed deadlines and measures necessary for complete conformity with articles 34-36 TFEU.

Regulation 764/2008/EC contains procedural rules for the application of mutual acknowledgement principles in EU member states, and which refers to products made in accordance with requirements of national technical regulations. This legal act refers to products that are not subject to harmonized technical legislation of the EU and provides that each member states has points of contact capable of giving required information on contents of technical regulations and administrative measures concerning products encompassed by national regulations to all economic entities, especially to other member states. It is not necessary to adopt this regulation into the domestic legal system before Sernia's accession to the EU. However, contact points should be established in all ministries competent for enacting technical regulations. Contact points will have the task of providing exhaustive information to foreign and domestic economic bodies on the contents of technical regulations from their jurisdiction.

A large number of state administration bodies with different jurisdictions will be involved in enacting and implementing technical regulations, making this whole field very complex. Considering that ministries competent for enacting and implementation of technical regulations must raise professional and administrative capacities and constantly work on educating state employees and supervise their implementation. Aside from that, the work of these ministries should be well coordinated so technical regulations governing all aspects referring to a specific group of products can be enacted in due time, and in order to avoid unclear and contradictory requirements for marketing and/or use of said products, with ensuring of coordinated market surveillance exists over implementation of technical regulations from different fields referring to related products.

3.2. Status of the Serbian Quality Infrastructure System

3.2.1. Metrology

The first form of institutionalized metrology activities in the former Kingdom of Yugoslavia was established in 1873, when the first Law on Measures which introduced the decimal metric

system based on French archive prototypes of metre and kilogram, was enacted. The Principality of Serbia joined the Metre Convention as a Member State, 1879.

The current Metrology system in Serbia was created in accordance with international and European trends and consists of following institutions: ministry in charge for metrology which creates strategy and politics of metrology development, Directorate for Measures and Precious Metals (DMDM) as national metrology institute and Metrology Council as advisory body established by the Government of the Republic of Serbia. Further bodies that play an important role in the metrological system include: state authorities and other subjects that are active in the field of obtaining, maintaining and improving national etalons, authorized bodies for verification of measuring instruments, accredited laboratories for calibration and designated conformity assessment bodies.

DMDM is state authority, which acts as the main pillar of the whole metrology system in the Republic of Serbia. Regarding Law on metrology, DMDM is in charge of legal, industrial and scientific metrology. DMDM is also in charge of the enforcement of Law on control of articles made from precious metals and the Law on calculation of time. It performs both professional and related administrative activities in the field of metrology listed in these laws.

DMDM as national metrology institute (NMI) of the Republic of Serbia performs research in the field of metrology, enables traceability over national etalons to international etalons of SI units, provides traceability of measurement results for all interested parties to national and international level, develop and enhance calibration methods, performs calibration of measuring instruments and provides necessary professional help to accredited laboratories for calibration and other users.
DMDM became a signatory to the CIPM MRA in 2002 for its specific competence in the field of calibration and measuring (CMC), published in the database of International Bureau of Weights and Measures (BIPM KCDB) and, in that respect, is involved in appropriate key and additional comparisons in certain fields of metrology. DMDM has published 191 CMC in following fields: electricity and magnetism, dimension measurement, photometry, temperature, time and frequency and volume. In these fields, Serbian national metrology standards (etalon), etalon related certificates and measuring results issued by DMDM are recognized on international level by all NMI that are signatories of CIPM agreement.

DMDM is also in charge of legal metrology tasks, which especially encompass: assessment of conformity of measuring instruments prescribed in the Rulebook on measuring tools and the Rulebook on non-automatic scales (that introduced the European directives MID and NAWI into the legal system of the Republic of Serbia), testing and approving types of measuring instruments, testing of pre-packed products, metrological surveillance (surveillance off measuring tools and pre-packed products), surveillance of use of legal measuring units, certification of measuring instruments for which there are no competent bodies, involvement in drafting regulations in the field of metrology, metrological expertise, etc.

DMDM represents the Republic of Serbia in international and regional metrology organizations and cooperates with other countries in the field of metrology. DMDM actively participates in the work of these organizations. Republic of Serbia is member of Metre Convention and International Bureau of Weights and Measures (BIPM) for mass and weight from 1879 and member state and founding state of International Convention establishing the International Organization of Legal Metrology (OIML) from 1955. DMDM has also been a member of the International Association of Assessing Officers (IAAO) since 2002. On the European level, DMDM is member of metrology organizations EURAMET и WELMEC. DMDM became member of EURACHEM in 2013 and is a contact organization, through which other organizations in Serbia can get involved in the work of EURACHEM.

DMDM is a signatory of the most important agreement on recognition of metrological service of the International Bureau of Weights and Measures (CIPM MRA). This agreement allows tracing through national standards to international standards of SI units to all users in the Republic of Serbia. By the July of 2013, 127 specific capabilities for calibration and measuring (CMC), realized by the DMDM were published in the database of the International Buerau of Weights and Measures (BIPM KCDB). That ensured the worldwide recognition of Serbian national standards, calibtration certificates and results of measurements published by DMDM in all fields.

In the fields of measurement for which national standards of the Republic of Serbia are not realized, interested parties will provide tracing in the NMIs other signatory states of the CIPM MRA or in the laboratories for calibtration accredited by the accreditation bodies of signatories of appropriate arrangements on mutual accreditation recognition.

Law on metrology provides that, in exceptional cases when DMDM is not capable, and other state authorities and economic bodies can keep, maintain and improve certain national standards. Some of the existing scientific institutes in the Republic of Serbia have capacities, appropriate experience and knowledge to become bearers of national standards. During 2014, national Institute of nuclear sciences "Vinča", Belgrade (INS "Vinča") has been named as the bearer of the national standard in the field of ionizing radiation which allowed the INS "Vinča" to be on the list of institutes participating in the agreement on mutual recognition of standards, measuring results and calibration certificates (CIPM MRA).

The field of legal metrology is regulated by the Law on Metrology and Rulebook on types of measuring instruments which need to be verified and time interval of their periodical verification (Official Gazette RS Nr. 49/2010). The Rulebook describes that in Serbia there are 37 different measuring instruments that are subject to mandatory checking and validation, of which 28 are subject to conformity assessment in advance, which is performed by DMDM as a type approval.

Having in mind that software testing for measuring instruments plays an important role in assessing conformity of most modern measuring instruments, as well as that DMDM has not done that until now, it is necessary to enable it for this type of testing.

Aside from DMDM, certification of measuring instruments is also done by competent bodies whose work is supervised by the DMDM. Until October of 2014, 75 bodies were authorized for more than 20 measuring instruments. DMDM performs metrological surveillance of measuring instruments and pre-packed products which are placed on the market as well as surveillance of measuring instruments in use. Surveillance comprises surveillance plans as well as tackling complaints from consumers and other stakeholders. Furthermore, DMDM also supervises the use of legal units of measure.

Controls in metrology surveillance in 2011 and 2012 demonstrated that a big number of measuring instruments on the Serbian market were not inspected (scales on green markets and groceries, taximeters, liquid gas measuring devices, tanks, electric meters and water meters, humidity meters a.o.) which was a consequence of many years of not performing metrological surveillance. In 2013, the situation improved significantly, especially when it comes to certifying scales on markets and stores as well as measuring tools used in lines for technical inspection of vehicles. That is, also, a result of increased metrological supervision in these fields. Examination of pre-packed products, including measuring bottles, in terms of the Rulebook of pre-packed products is the new task for the DMDM and in that sense, necessary activities for its realization in the last two years.

Regarding participation in European research programs DMDM has had the possibility of taking part only in a very small number of programs, s.a. EMPR particularly in *Researcher Mobility Grants,* in the field of energy and SI Broader Scope. Aiming at improvement of knowledge and competence of DMDM experts in scientific metrology, calibration and measuring, participation of DMDM in relevant research projects should be intensified.

3.2.2. Standardisation

The first form of institutionalized activities on adoption of standards was established in 1946.

Today standardisation in the Republic of Serbia is based on acknowledged principles of the Agreement on Technical Barriers to Trade (WTO/TBT), which include the involvement of all stakeholders, consensus, transparency, comprehensiveness, voluntariness and non-discrimination.

Law on standardization from 2009, in the time of its adoption was fully aligned with EU acquis and transformed ISS into non-profit institution outside the public administration.

Organs of ISS are assembly, managing board, director and supervisory board. Furthermore, there are expert councils and committees, as expert bodies which are established for provision of guidance in some fields of standardization and with the purpose of adoption of standards and relevant documents.

Status and work of ISS and other issues related to standardisation are regulated by Law on standardisation (Official Gazette of RS, No. 36/09), Decision on the Amendments to the Act on the Establishment of the Institute for Standardization of Serbia (Official Gazette of RS, No. 88/09),as well as Statute of ISS (Official Gazette of RS, No. 06/11).

Basic activities of ISS, as sole standardization body in the Republic of Serbia, are adopting of standards, ensuring the compliance of Serbian standards with international and European standards, interpretation of standards, official notification of standards in accordance with the requirements foreseen in the relevant international agreements and obligations arising from membership in international and European standardization organizations, as well as the sale of standards and the provision of services in connection with standardization.

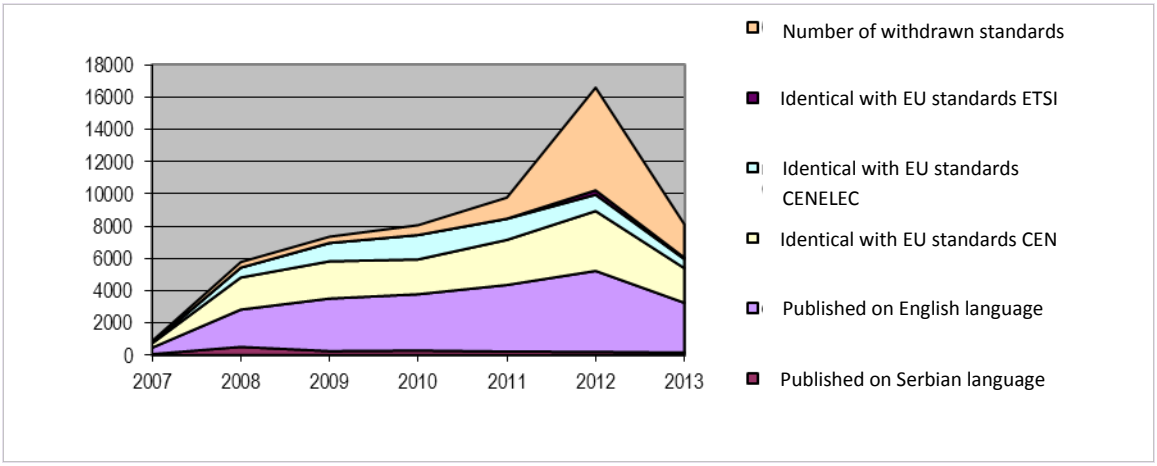
In preparing the annual work programs of ISS and annual plans of adoption of Serbian standards and related documents, above all, priorities arising from the process of Serbia's accession to the WTO and SAA are taken into account, which define the obligations that Republic of Serbia must meet before joining the EU.

ISS has been a full member of ISO – International Organization for Standardization since 1950. and IEC – International Electrotechnical Commission since 1953. It became an affiliate member of CEN – European Committee for Standardization in 2008 and of CENELEC – European Committee for Electrotechnical Standardization in 2005.

Full membership of ISS in CEN and CENELEC is one of the preconditions that Serbia has to fulfill in EU Accession process. One of the preconditions for full membership in above mentioned organizations was adoption of 80% of European standards and harmonized documents into the Serbian standardisation system.[3] This was fulfilled in the way that ISS, until the end of 2014., adopted 95% of European and 97 % of European harmonized standards. The dynamics of European standards adoption is shown on the following graph.

[3] These documents are published by CENELEC and they have the same status as European standards.

GraphNr. 5: Dynamics of the European standards adoption



Preparatory activities necessary for applying of ISS for full membership in European organizations are ongoing.

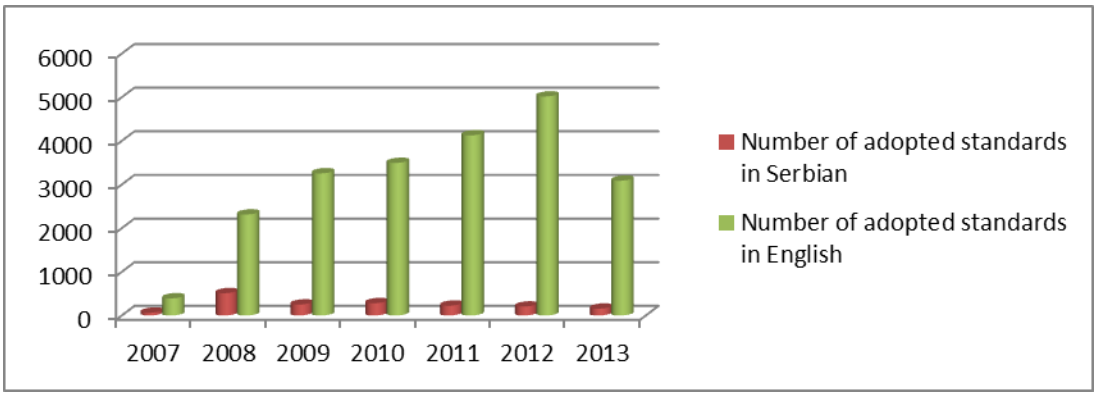
ISS functions as information center for standards, providing information related to standards according to requirements of WTO/TBT and European level – Directive 98/34, which prescribes procedures for provision of information in the field of standards and technical regulation.

By adoption of the Law on standardisation, some novelties were introduced in Serbian legislative system. The most important was abolishment of mandatory use of more than 8.000 standards. In this way, one of the crucial requirements of the WTO Agreement on Technical Barriers to Trade (TBT) was fulfillled. Additionally, enforcement of this Law enabled faster and more efficient adoption of standards, which were based on European standards and standardization deliverables, and if they do not exist, international standards or national standards of other countries are used as the basis for adoption.

Realization of the five-year-plan for adoption of EU standards enabled ISS to perform activities regarding CEN and CENELEC in parallel. In other words, every new published European standard will be adopted as Serbian standard within the timeframe that is valid for all full members of CEN and CENELEC.

Even though the process of the “rapid” adoption of European standards is finished, less than 10% of European standards have been translated into Serbian.

GraphNr.6: Proportion of EU standards translated into Serbian language on annual basis



Translation of standards into Serbian is needed because the users often do not understand and therefore cannot apply English standard versions, which is very important especially if technical

regulation refers to these standards. Translation of standards into Serbian is connected to high costs, and ISS does not have sufficient financial resources for this purpose. Nevertheless, the ISS, members of expert bodies of the ISS, as well as state administration bodies are making efforts in order to provide a greater number of standards translated into the Serbian language.

Parallel to adoption of new standards, withdrawal of standards is taking place. Having in mind that technical regulations in non-harmonized area are often referring to standards in the process of withdrawal, a better coordination between ISS and line ministries is needed in order to assure updating of technical regulations and related standards.

Standardization is activity performed in the interest of direct and indirect users of standards and depends on their active participation. Participation in technical committees for standards is voluntary and free of charge and organizations that appoint their representatives bear eventual expenses.

Although participation costs are minimal and include only travel expenses and per diem expenses for committee members, current state of Serbian economy and finacial crisis do not contribute to the motivation of private sector for investments in the field of standardization.

This is the direct consequence of lack of awareness on importance of standard application and knowledge of requirements of standards and related technical requirements.

On the other hand, number of ISS technical committees is high, and many of them are inactive and not efficient enough. Main reason for this is lack of interest of economic operators and other institutions for appointing their representatives in committees. Furthermore, the small number of members of some committees does not assure balanced representation of all major stakeholders and is not fully in line with their needs.

Both of these problems are direct consequence of lack of awareness on importance of standard application and knowledge of requirements of standards and related technical requirements.

On it's way to full membership in CEN and CENELEC, ISS has to train experts, representatives of economic operators in committees, for participation it the work of technical committees of this organizations especially in the areas of standardisation that are of the interest for Serbian economy.

In order to achieve this, awareness raising regarding importance of standardization and standards as public good is needed. Additionally, young experts should be trained for the purpose of definition and representation of Serbian interests in certain areas of standardisation which shall be included in the work of technical committees of European standardization organizations. Nevertheless, compensation of costs should be assured (daily allowances, travel costs).

Modern standardization is not possible without application of the up-to-date ICT solutions. Great amount of data have to be transferred and processed in a most efficient way, enabling easy transfer of the selected information and quick finding of certain items during the whole working process. Challenges for ISS will increase with CEN CENELEC upcoming membership. ISS will put therefore additional efforts for continuous development and maintenance of adequate level of ICT equipment and belonging data bases as well as for preparing and enabling human resources to response these challenges.

Regarding financing, ISS is mostly financed from the budget of the Republic of Serbia and the smaller part - 30% is from its own recourses (sales of standards, membership fees, interpretations of standards, trainings, etc.).

In 2011 ISS started organizing and conducting seminars as a service for public and private sector. As the first results are encouraging, ISS plans to develop a Training Center for providing services for a broad specter of needs and interests of standardization stakeholders. Performing these

and other additional activities, ISS would be able to assure stable alternative source of financing, which is one of the requirements for full membership in European standardization organizations. A change of the Law on Standardization is required in order to enable performing of certification service as well, which was performed by ISS till 2009 and is the practice of many European standardisation bodies.

In addition, the Law on Standardization, which was adopted in 2009, introduced the possibility of voluntary conformity assessment of products, processes and services with Serbian standards, which has resulted in the issuance of certificate of conformity with these standards, or placing a voluntary mark of conformity with Serbian standards from the manufacturer or service provider. Voluntary conformity mark may be a national mark, owned, issued and monitored by the ISS, or the scheme can be oprated by other CAB, based on voluntary certification. In addition to promotion and awareness raising of the importance of standardization, ISS activities on creating and approving the usage of voluntary national conformity mark may contribute to establishment of stable alternative source of funding.

3.2.3. Accreditation

The first form of institutionalized accreditation activities was established in 1998, by establishing of Yugoslav Accreditation Body (JUAT) as a part of state administration.

Since 2007, Accreditation body of Serbia has been the only national accreditation body in the Republic of Serbia, which became a public institution in 2010. The Law on Accreditation ("Official Gazette of RS", No. 73/10) entrusted Accreditation Body of Serbia for performance of all accreditation activities.

Status and work of ATS and other issues related to accreditation are regulated by the Law on accreditation, Decision on changes and amendments of the founding document of the Accreditation Body of Serbia (Official Gazette RS Nr. 14/11) and the Statute of the Accreditation Body of Serbia (Official Gazette RS Nr.97/11).

In addition to the accreditation, ATS performs the following tasks: develop and publish the rules of accreditation, which are based on the relevant Serbian, international and European standards and documents of international and European organizations for accreditation; maintain a public register of accredited CABs; participate in the work of international and European organizations for accreditation; performs other activities in accordance with the Law, founding act and the statute.

The Law on Accreditation is adopted in order to harmonize accreditation system in Republic of Serbia with EU legislation and standardized requirements as described bellow:

a) Regulation 765/2008/EEC for regulation of requirements for accreditation and market surveillance regarding placing products on the market and
b) Standard ISO IEC 17011 Conformity Assessment – General requirements for accreditation bodies that provide accreditation for conformity assessment bodies

The accreditation system in the Republic of Serbia is based on the following general European principles of accreditation:

1. Every European country appoints one national accreditation body. In Serbia, this is ATS;
2. National accreditation body has to be organized in manner that ensures objectivity and impartiality. ATS's organization is prescribed by Law and meets the requirements of ISO IEC 17011;

3. National accreditation body is a non-profit organization; Republic of Serbia assures that ATS has adequate financial and human resources for functional performance of tasks. ATS is mostly (85%) financed from its own resources (charging accreditation fees), and only a small part (15%) from the budget of the Republic of Serbia and other sources in accordance with the Law;
4. National accreditation body is not allowed to be in competition with conformity assessment bodies. According to the Law, ATS is not allowed to either perform activities and services that are offered by conformity assessment bodies or to offer consultancy services or to have any kind of financial or managerial interest in conformity assessment bodies in order to prevent conflict of interest;
5. All stakeholders should be involved in the work of national accreditation body. The Law has assured balanced and effective participation of all stakeholders in the work of ATS;
6. National accreditation body has to provide to conformity assessment bodies a procedure for dealing with complaints. Management board of ATS has established a Committee for complaints according to the Law;
7. National accreditation body obeys principles of the cross-border accreditation. In the case that ATS is not performing accreditation in the fields that a conformity assessment body seeks accreditation for, ATS can advise to apply for accreditation by accreditation body of an another country.

Basic activity of ATS is determination of competence of the conformity assessment bodies for testing, calibration, inspection and certification of products, management systems and persons, as well as PT providers and verification of EMAS and ETS.

Accreditation Body of Serbia (ATS) became a member of the EA in May 2012 by signing a Multilateral Agreement (MLA) with EA on recognition of the national accreditation for: testing laboratories, medical laboratories, calibration laboratories, inspection and certification bodies for product certification. In the first half of 2014 the coverage of EA MLA was extended to certification bodies for management systems and certification of persons. This agreement was signed based on results of peer evaluation by EA according to Regulation 765/2008/EEC. By signing this agreement, equivalence of the national accreditation system with the system of accreditation of the EU countries was confirmed and precondition for acceptance of conformity assessment certificates issued by conformity assessment bodies accredited by ATS.

ATS, as a member of the International Laboratory Accreditation Cooperation (ILAC) is also signatory of several agreements such as ILAC MRA (Mutual Recognition Agreement) in the field of testing, calibration, inspection ect. ATS is a member of the International Accreditation Forum (IAF) and signed IAF MLA for product certification and certification of systems of management.

ATS organs are management board, director and supervisory board. Advisory organs of ATS are Accreditation Council and number of permanent or temporary committtees.

The Accreditation Council is a technical advisory body of ATS that: provides professional opinions as regards development of the accreditation system; initiates the extension of the ATS scope of activities; comments on application of standards for accreditation in some field; makes proposals on establishment of permanent and temporary technical committees for certain fields of accreditation. Council is consisted of 11 members – stakeholder representatives.

Technical committees are technical bodies providing expertise required for certain fields of accreditation. They provide the interpretation of the requirements and documents of international organizations in certain types and areas of accreditation, considering proposals from EA, ILAC/ IAF documents, provide assistance to the ATS in the field of expansion activities, establish criteria for

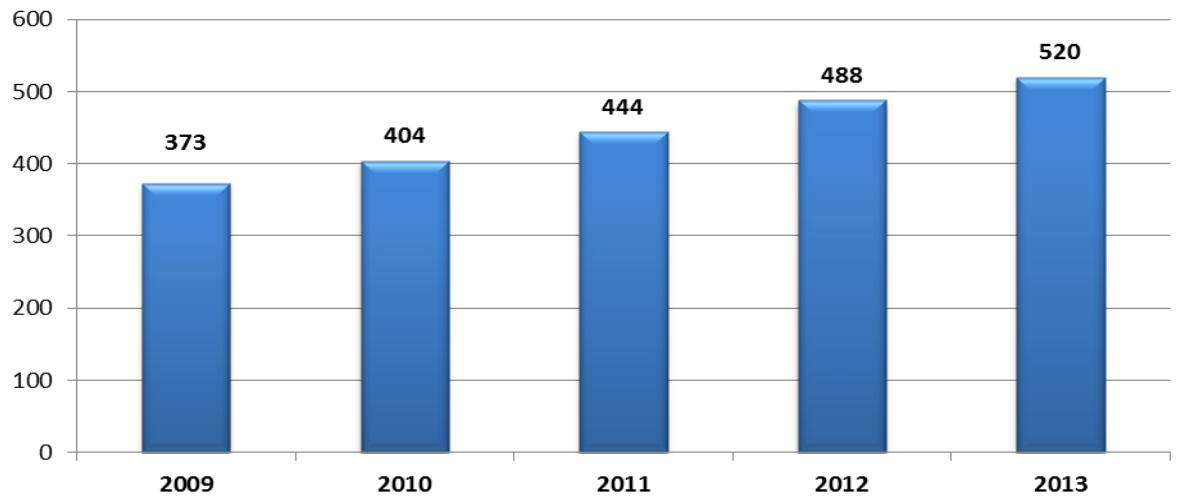
assessors competency in certain areas of conformity assessment, identify potential assessors and provide assistance to ATS regarding recognition of inter-laboratory comparisons (PT schemes).

The ministry in charge of accreditation supervises the work of ATS, and ATS supervises the work of accredited conformity assessment bodies.

Until September 2014 ATS issued accreditation for 527 conformity assessment bodies (CABs) in total:

Type of accredited conformity assessment body	**Number**
Testing laboratories SRPS ISO/IEC 17025	301
Calibration laboratories SRPS ISO/IEC 17025	52
Medical laboratories SRPS ISO 15189	10
Certification bodies for product certification SRPS EN 45011	20
Certification bodies for product certification ISO/IEC 17065	2
Inspection bodies SRPS ISO/IEC 17020	129
Certification bodies for quality management systems ISO/IEC 17021	11
Certification bodies for certification of persons ISO/IEC 17024	2
Total	**527**

GraphNr.7: Number of accredited CABs in last 5 years



In accordance with 765/2008, ATS must have available adequate resources, both financial and human for proper performance of its tasks.

ATS must provide a sufficient number of competent staff (employed ATS assessors and technical experts) to be able to respond to the demands of the economy or CABs, and in order to ensure that accreditation procedures are carried out in a competent and proper manner and within specified timeframes.

At the moment, in the Register there are 257 leading assessors/ technical assessors and technical experts, out of that: 60 leading assessors, 113 technical assessors and 142 technical experts.

Standards	Number of leading assessors
ISO/IEC 17025	43
EN ISO 15189	3
ISO/IEC 17020	16
ISO/IEC 17065	6
ISO/IEC 17021	8
ISO/IEC 17024	2

Standards	Number of technical assessors
ISO/IEC 17025 LI	70
ISO/IEC 17025 LE	20
EN ISO 15189	11
ISO/IEC 17020	21
ISO/IEC 17065	3
ISO/IEC 17021	8

Additionally it is necessary to constantly monitor changes of technical regulations and in accordance with these changes to ensure effective implementation of accreditation of CABs for the purposes of designation or authorization.

3.2.4. Conformity Assessment

Conformity assessment as one of the major elements of a national quality infrastructure means checking whether products, services, materials, processes, systems and personnel measure up to the requirements of standards, regulations or other specifications. In this way Conformity Assessment benefits manufacturers, service providers, users, consumers health and safety and to regulators. Furthermore conformity with harmonized standards creates confidence and facilitates access to world markets.

Conformity assessment covers different activities from testing, inspection, process evaluation, product certification, management system certification and personnel certification.

The World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement) was established to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not create unnecessary barriers to international trade.

Assessment of conformity with safety and other technical requirements prescribed by the law has to be conducted in order to assure that only safe products are placed on the market. This is one type of control before placing products on the market.

Law on Technical Requirements for products and conformity assessment from 2009 creates the legal basis for prescription of technical and other requirements for products in National Technical Regulations, i.e. for the regulation of conformity of products with prescribed requirements. At the same time it is a legal basis for adoption of European harmonized technical legislation of new and old approach as well as for introduction of indigenous Serbian technical regulation in the non-harmonized area.

The main novelties introduced by this Law:

- Decentralized adoption of technical regulations by line-ministries;
- Precise clarification of obligations and responsibilities of economic operators who participate in product-placement in the Serbian market;
- Introduction and precise definition of the terms “designation” and “authorization” of economic organizations, institutes and other legal entities which perform and participate in conformity assessment (CABs) respectively.

Conformity assessment is mandatory when prescribed by a technical regulation or voluntary if the conformity of the product is assessed according to standards or other voluntary technical specifications. According to the law conformity assessment of products can be performed by producers, designated conformity assessment bodies or by state authorities for products with a higher risk-level, which is determined by a special technical regulation. Special laws may prescribe also other entities that can conduct conformity assessment.

The Law foresees that technical regulation can determine obligation for conformity assessment of products and in concrete technical regulation are listed different methods (modules) for conformity assessment which can be applied depending on the type and complexity of the product, respectively the type and level of the risk during the use of the product.After a succesfully performed conformity assessment procedure the prescribed conformity certificate is issued and labeling of the prescribed (Serbian) conformity mark is carried out.

Serbian conformity mark is the only mark confirming that a product placed on the market or usage in the Republic of Serbia, complies with the requirements of Serbian technical regulations, if these regulations foresee its afficing.

According to the law and the by-law that governs designation and authorization, Ministers of the line ministries in accordance to their field of work designate/ authorize conformity assessment bodies. Designated bodies conduct conformity assessment for the needs of the producers, and authorized bodies for state authorities. In order to be designated/ authorized a CAB has to fulfil requirements deriving from the technical regulation. Expertise and technical competence of CABs is proved by accreditation or other relevant documentation, which competent authority shall take into consideration when deciding on the designation or authorization. Ministry in charge of economy keeps the register of designated and authorized CABs. 34 CABs were designated in different fields until October 2014.

CABs operating in Serbia regardless of being domestic or foreign regardless of being designated or just accredited are organized since 2013 on voluntary basis in the association of CABs at the Serbian Chamber of Commerce and Industry (SCCI). Some certification bodies are members of the “association of independent accredited bodies” (ANAT) which is member of EFAC. Nevertheless in the recent years ANAT has shown no signs of activity. There is an obvious need for specialized CAB associations for different areas of conformity assessment and accreditation.

All analyzed CABs are aware of the importance of accreditation and the added value that it brings. Lack of specialized associations, which would represent their interests, is considered as a significant weakness. This kind of representation is successfully practiced in almost all countries with functional QI infrastructures. There were complaints about unethical behavior and unfair competition of certain CABs in the field of management system certification. It is necessary to consider the establishment of a central registry of certification bodies in the voluntary area that could contribute to fair market relations. Also cross-border accreditation could be better promoted in accordance with the EA policies, in collaboration of ATS and such association. In addition, the advantages of a specialized CAB association are: better cooperation with regulators and industry; increasing availability of conformity assessment services to the industry; establish effective cooperation with ATS, ministries and chambers; more operational resolving of complaints of unethical behavior of CABs; securing membership in the relevant European associations, which contributes to the transfer of knowledge and good practice.

The demand for organization of inter laboratory testing (proficiency testing – PT scheme) is obvious among CABs, because participation in these schemes is one of the criteria for maintaining the status of accredited CAB. Bearing in mind that ATS began the accreditation activities of the first PT provider during 2013,, it is necessary to encourage other interested PT providers from other areas for which there is a need in the market to be accredited.

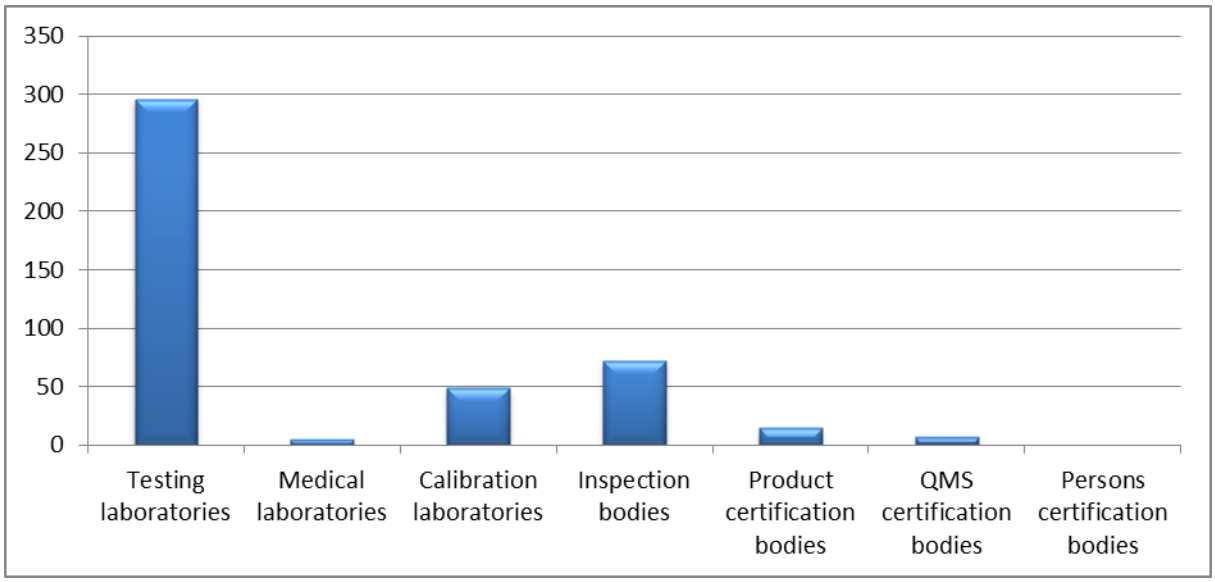
Having in mind that accreditation is voluntary and motivated with economic interest of CABs, obvious problem is that in some areas there are no accredited bodies.

On the other hand a significant number of accredited CABs, even though they have the economic interest are not in position to extend their scope of accreditation, due to the lack of financial, technical and human resources.

Having this in mind and the fact that accreditation is the best way of proving competence of CAB, in certain areas there is not sufficient number of designated CABs, which is an essential condition for the full implementation of technical regulations.

The analysis showed that a certain number of CABs has no adequate attitude towards customers in terms of effective and timely response to submitted requests regarding conformity assessment and complaints about their work, which may be the result of inefficiently applied management system. This situation could be improved with trainings, to train CABs to effectively implement and further develop the established management system. It is evident that the number of accredited testing laboratories is dominant in relation to the number of other accredited CABs.

Graph Nr.8: Number of accredited CABs



3.2.4.1. Product certification

Product certification is the activity concerning evaluation and confirmation of product-compliance with prescribed requirements. The certification process results in the issuing of a certificate by the certification body. Product certification usually includes product testing conducted by laboratories. Bearing in mind that not all certification bodies have their own testing facilities, they have to cooperate with laboratories.

For this reason, at the level of the European Community and in Serbia in the field of New Approach Directives it is considered best practice to grant the official designation to certification bodies and to testing laboratories involved in the process of conformity assessment for a given product.

Analysis conducted on a sample of domestic product certification bodies showed the following result:

- Practically all bodies dispose of competent staff, in a few cases the average age of employees is high to very high, endangering knowledge transfer. This can be solved by employment of younger staff and adequate trainings that do not require significant costs;
- Majority of bodies is well-recognized on the national market and has a sound and stable market position. Some bodies are also relatively well-connected with sub-regional and/or EU markets and customers;
- Investment in equipment will be necessary for the majority of bodies;
- Only a few certification bodies seem to be prepared for the future EU market, including the organizational and managerial aspects and the adequacy of their strategic and commercial planning. Unpreparedness of CABs for the challenges of new technical legislation (which does not foresee mandatory certification for a big number of products in comparison to previous legislation but introduces it for the first time for some other products) is reflected in the lack of perception the sustainability of existing activities in the medium and long term, or for a change in business orientation;
- The majority of CABs cooperates regularly with ISS and are represented in Technical Committee's

Accordingly, it is necessary to determine the needs of the Serbian market and the needs of economic development, in order to optimize market position and territorial representation of CABs. Certification bodies should in this way significantly contribute to the economic development and competitiveness of domestic producers.

Table No.2: SWOT analysis of domestic CABs

Strengths	**Weaknesses**
- Well-known bodies with good reputation; - Competent and experienced staff	- Inflexible and "heavy" organizational setup - Lack of strategic and commercial planning; - Insufficient networking with EU bodies and (potential) EU customers
Opportunities	**Threats**
- Maintain existing client base benefiting from "credit of trust"; - Win new clients through new services and fields of operation - connection and cooperation with CABS from EU using the advantages of EA MLA agreement signed, aiming attraction of new clients	- overwhelmed by strong EU competition after transition phase - the lack of an effective marketing strategy.

3.2.4.2. Testing Laboratories

The accreditation file register of ATS is a reliable source to have an exhaustive view in number and scope of accreditation of Serbian laboratories.

Currently, laboratories in Serbia are not organized in organizations or associations exclusively representing their interests. Respective organizations existing in the past are no longer active. Exceptionally, some 50 to 70 material testing labs from Serbia and the region are organized within "KOMIM" focusing only on PT purposes.

There is no official regional co-operation between labs. On case by case basis, some labs have agreements or co-operations with their counterparts from the region.

Laboratory assessment provided the following results:

- All visited laboratories are aware of value adding through accreditation;
- Lack of horizontal communication and institutional cooperation between labs is experienced as a big weakness;

- There is an obvious demand for the participation in interlaboratory comparisons in order to confirm professional competence of laboratories (PT schemes). Certain number of laboratories is interested in providing services of organization and managing PT schemes, i.e. for obtaining accreditation according to the standard SRPS ISO/ IEC 17043;
- Many managers and lab staff have serious difficulties in their professional client-relations including client expectations and deadline-keeping. If there was an efficient application of management systems this could have been overcome and certain correction measures would have been undertaken;
- There is a need for analysis of financial condition, especially cost-analysis and it is also evident a need for adequate training in the area of financial management;
- Only few labs are aware of the importance of designation and future notification in the EU respectively because they prefer some specific solutions presented by Serbian technical regulations, which exist in transition periods until EU membership. They are less oriented towards extension of accreditation scopes according to new harmonized standards which would serve manufacturers and market surveillance.

Table No. 3: SWOT analysis of domestic Labs

Strengths	**Weaknesses**
- Competent and experienced staff - Scientific background at high level for labs work; - Wide range of scopes accredited; - Competitive prices compared to international labs with international accreditation.	- Lack of strategic and business planning; - organizational structure that causes large fixed costs; - Missing market overview; - Change from authority to service provider; - Missing customer orientation; - Insufficient networking with EU bodies and (potential) EU customers; - Still lacking exhaustive knowledge of new legal framework, - aged equipment.

Opportunities	Threats
- availability of IPA funds and other projects; - client pool “credit of trust” and acquisition of new clients; - increasing importance of CE-marking and Triple A-marking; - Industry-awareness rising on responsibilities through “self -declaration.	- changes in demand for mandatory testing in certain areas, in accordance with the new regulation (in some areas mandatory testing will be abolished, in some it will be introduced); - strong EU/ international competition on the market, especially after transition phase;

3.2.4.3. Management System Certification

In production and services, management system certification is a widely accepted tool for companies to demonstrate compliance of their organization and business to the internationally recognized standards (which in turn reflect industrial best practice).

The three most popular management system standards are ISO 9001:2008 (quality management systems), ISO 14001:2004 (environmental management systems) and OHSAS 18001 (occupational health and safety management systems). In addition to these, there is another group of standards that are significant in certain areas. In this group of standards we find ISO 22000 (food safety management systems), ISO/TS 16949 (quality management systems for the automotive sector), ISO 50001 (energy management) и ISO 27001 (information security management). All mentioned standards have been identically adopted as Serbian standards.

Management systems certification is typically voluntary, as it is in the EU, but has an important role in the context of European legislation in the field of free movement of goods. It is an option for conformity assessment in the context of several modules according to Decision No 768/2008/EC. In line with this Decision, the legislator bestows on the results of quality management system certification, the presumption of conformity with the applicable technical regulation.

In Serbia, system certification activities are carried out either by domestic certification bodies, not all of which are accredited by the national accreditation body ATS, as well as foreign certification bodies accredited by foreign accreditation bodies (UK, Germany, Netherlands, Romania, Spain a.o.). Often foreign accreditation does not cover the territory of Serbia therefore there is no mechanism for surveilling their work, neither through foreign national accreditation bodies nor through ATS. For this reason operation of foreign CABs constitutes unfair competition.

Foreign CABs without Serbian accreditation are dominant on the market of management system certification service provision and these services are often offered through their representative offices or branches and often not even registered.

In accordance with the EA document which refers to the policy of cross-border accreditation, as well as Regulation 765/2008, since the end of 2014, all CABs accredited by international accreditation bodies, signatories of the EA MLA agreement, must be included in the national system

of accreditation or can operate with foreign accreditation only within the framework of "multi-site" accreditation (accreditation which specifies on which territories certificate of accreditation is valid).

Most management system certification bodies are accredited for two or more systems, so that they cover almost 80% of the maximum 39 areas (categories of) management system. Although in some areas certification bodies have relatively little activity, they keep them within the scope of accreditation for reasons of competitiveness. As a result, in these areas, despite the high academic qualifications, practical experience in knowing the processes is at a low level. Therefore, the practical knowledge and skills of assessors is difficult to maintain on the required level or to improve them.

According to the ISO survey, (conducted in 2012), system certification is strongly growing certification sector in Serbia. The most relevant standard was SRPS ISO 9001 and Serbia is one of the countries with the highest growth rate of these certificates in the world. This growth rate was mainly caused by foreign certification bodies, especially their representative offices or branches. Environmental management systems according to SRPS ISO 14001 are not nearly as significant in terms of the number of certificates, and the same is true for SRBS EN ISO 22000. Certification in accordance with technical specification SRPS ISO/TS 16949, defining the application of ISO 9001 for the automotive industry, is a very small certification market niche. No national data exist for SRPS OHSAS 18001 and SRPS ISO/IEC 27001 (information system management).

Table No. 4: Number of certificates issued by type

Standard	Number of issued certificates per year				
	2008	2009	2010	2011	2012
SRPS ISO 9001 (quality management system - QMS)	2091	2733	1790	3228	3066
SRPS ISO 14001 (environmental management system - EMS)	176	298	318	573	817
SRPS EN ISO 22000 (food safety management systems)	17	-	-	-	172
SRPS ISO/TS 16949 (application of standard ISO 9001 in automotive sector)	-	-	-	-	18

Conducted assessment of domestic management system certification CABs regarding their readiness for active participation on the European market provided the following results:

- All interviewed system certification bodies offer SRPS ISO 9001, SRPS ISO 14001, SRPS OHSAS и SRPS EN ISO 22000 as system certification schemes. The majority of the certification bodies were able to cover all relevant scopes (max. 39), except nuclear energy, ships and aircraft. Three certification bodies co-operate with international partners;

- All certification bodies were accredited by ATS, some of them also by other international accreditation bodies;

- The fact that ATS until the end of 2013 was not yet a signatory to MLA in the field of management system (MS) certification was a problem for Serbian local certification bodies, as their certificates were not recognized outside of Serbia. On the other hand, foreign certification bodies without ATS accreditation issued certificates that are accepted on all markets and that was disadvantage for domestic CABs. In 2014 the existing MLA agreement between the ATS and EA was extended to also cover accreditation of certification bodies for management systems and persons and it is necessary to monitor how this will affect solving above mentioned problems;

- Currently there is no CAB that has been designated according to some of the conformity assessment modules referring to quality management systems;
- It was observed that the Serbian industry as client currently mainly follows a formal approach to the implementation of management systems. Industry sees the need to obtain certifications if clients ask for them, for example in case of public procurement, but QMS implementation seldom seems to be driven by the intention to pursue continuous improvement schemes.
- The financial crisis leads to budget cuts for quality management in certified companies. The number of operators dropping out of system certification completely has steadily grown in recent years. This situation leads to "a race to the bottom" amongst the certification bodies in Serbia, with the ones with the lowest requirements and the cheapest service offer rapidly increasing their market share.

Table No.5: SWOT analysis of domestic CABs for Management System Certification

Strengths	**Weaknesses**
- Wide range of scopes accredited; - Competitive prices compared to large CAB with international accreditation .	-Low market share comparing foreign certification bodies; - Lack of practical experience of assessors to cover all accredited areas
Opportunities	**Threats**
- Promoting the benefits that fundamental implementation of management systems brings; - Reforms in public procurement and public sector will promote implementation of management systems and open new markets	- Economic operators are not aware of the added value of management systems; - Unfair competition by non-accredited CABs - competition of CABs with international accreditation - Price decline of Management System Certification services; - Demand decline of Management System Certification services.

Results of foreign CABs assessment operating on Serbian market (branches, representative offices) indicate that these bodies:

- Cover a wider range of management systems certification, because they operate within large multinational companies;
- They are focused on recognizing their clients' needs and expectations, current and potential demand and attach great value to customer relations management;
- Majority is not accredited by ATS but most of them have accreditation by several foreign accreditation bodies;

- None of the international CABs in the survey see imperfections in their own organization and functioning. However, they point out the lack of qualified auditors and technical experts;

- None of the CABs seem to buy their standards through ISS, but use their networks instead.

Table No.6: SWOT analysis of foreign CABs for Management System Certification

Strengths	**Weaknesses**
- Large service portfolio - Quick and efficient service delivery	- Not accredited by ATS (which is often expected by local clients) - Foreign accreditation often does not cover the territory of the Republic of Serbia, and there is no annual monitoring (unreliability of foreign accreditation for domestic clients); - Not always affordable for local SMEs
Opportunities	**Threats**
- Increase the number of entrepreneurs who are interested in the implementation and certification of management systems; - Reforms in public procurement and public sector, will promote implementation of management systems and opening new markets .	- Reduced demand for new and/or different services in the field of management system certification. - higher price of service because of forgein accreditation

3.3. Industry needs in the field of QI

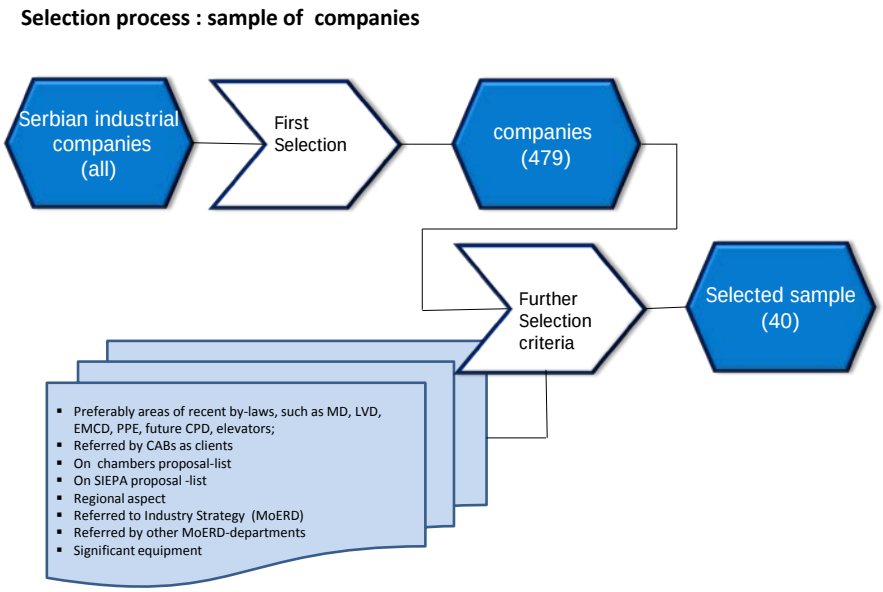
In order to assess current and future needs of the industry regarding support provided by QI system, Ministry of Economy together with GIZ ACCESS Program conducted an analysis based on the representative sample of economic operators, dominantly from the field of machine building industry, electro-technical industry, metal processing industry, construction products, pressure vessels etc. At the same time, the analysis included an analysis of functionality of the newly established legislation in the field of safety of product on the market.

Selection of the economic operators is performed based on available data from the Agency of registers of economic operators (APR), Serbian Chamber of Commerce and Industry (SCCI), Serbia Investment and Export Promotion Agency (SIEPA), Sector for Industry in the Ministry and list of of CABs. (Graph Nr. 9) and following criteria have been applied:

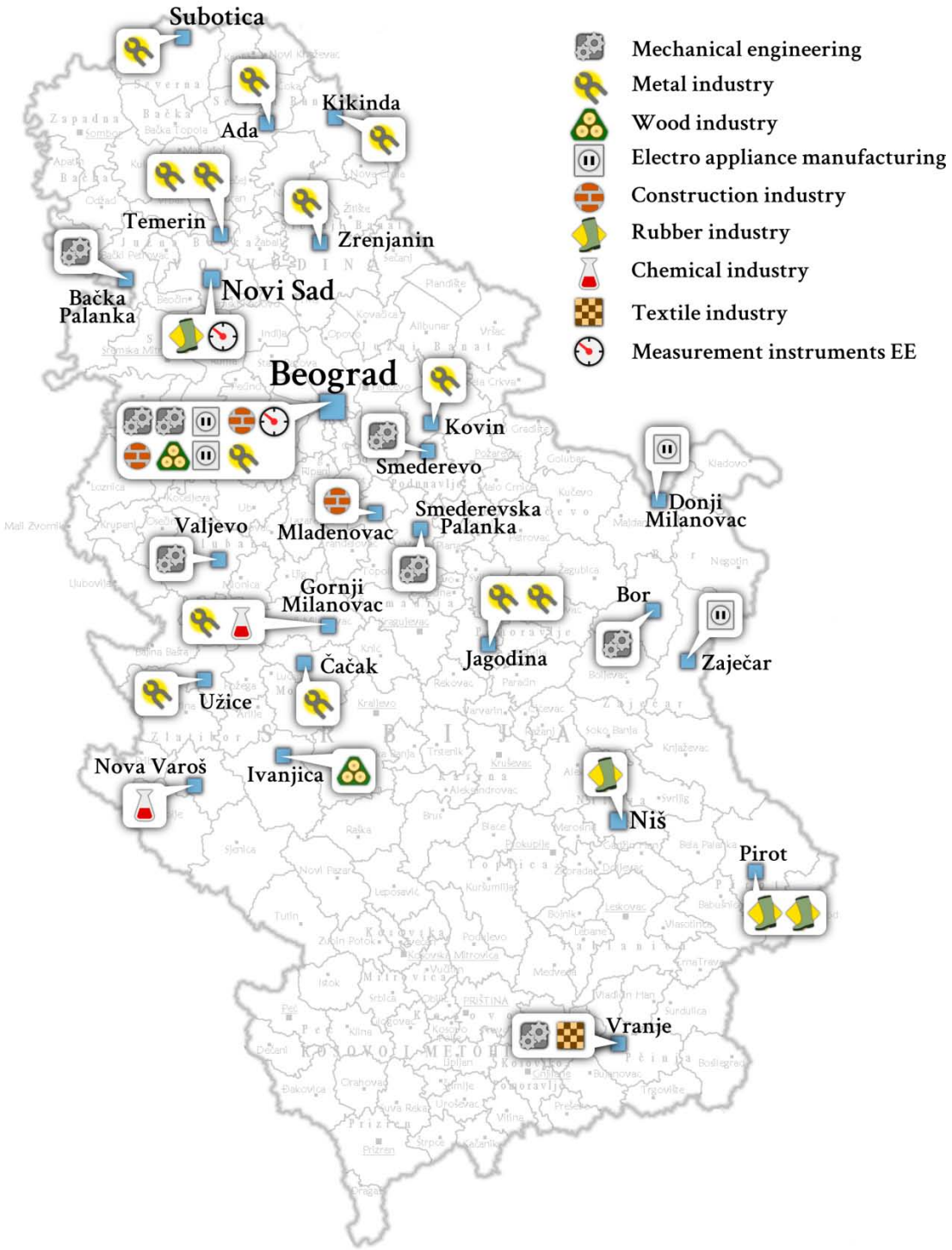
- Activity of the economic operator in priority sectors identified in strategic development documents;
- Participation of the economic operator in exporting business;
- Field of operation covered by harmonized EU laws: MD, LVD, EMC, PPE, lifts, CPR, pressure vessels;
- regional aspect of economic operator;

- Impact of economic operator on the encouraging the economic activities of other business entities.

Graph No.9: Selection process of industrial companies within the analysis of industry needs



Graph 10: Territorial distribution of economic operators by industrial branches that are included in the analysis



Original map image source:
Ytop, Administrative divisions of Serbia as of late February 2008,
http://commons.wikimedia.org/wiki/Atlas_of_Serbia

Analysis of the industry needs referred to the knowledge of and implementation of technical regulation, application of European standards, certification of products and management systems (QMS, EMS, OHSAS, and etc.) as well as analysis of the related needs of economic operators regarding QI services.

When it comes to the level of knowledge regarding requirements of technical regulations based on the EU "New Approach" Directives, assessment showed that economic operators believe that they are indeed aware of them due to the fact that 80% of them stated that they have excellent knowledge of. However, a more detailed analysis showed that only half of the number of these economic entities essentially knows and apply requirements of technical regulation.

Typical problems mirroring lack of knowledge regarding technical regulation are: multiple "third party" certification even in cases that this is not required by the technical regulation; neglecting of obligation to obtain domestic certificates of conformity and Serbian conformity assessment mark assuming that it is obsolete when it comes to the products already bearing CE mark, placing them on domestic market.

Economic operators which are preparing for the EU market tend to apply all EU technical regulation, but in some cases, they face difficulties due to the fact that harmonized national legislation is somewhat deviating from EU legislation. These deviations are introduced in transition period (until EU membership or signing ACAA) so that economy can prepare for transition from old legislation to new harmonized legislation as well as because the trade with countries beyond EU. An example of such a deviation is re-verification of product conformity (low voltage electrical equipment, machinery, radio and telecommunication terminal equipment), by declaration or certificate issued by designated body, although it is not required by European directive. The reason for this is to protect domestic market from non-safe products due to insufficient capacities and inefficient market surveillance in Serbia, which needs to take a new role according to the harmonized legislation.

Assessment showed that in the first years of implementation of the new technical regulation based on that New Approach directives are adopted, economic operators as well as CABs are somewhat disoriented. According to some reports, some CABs sometimes take advantage of ignorance of their clients and advise them to use some other conformity certificates instead of the ones that are required by the law. At the same time, CABs were adapting to the changes deriving from the new technical legislation very slowly, especially regarding implementation of new modules for conformity assessment and new kinds of certificates of conformity. This situation significantly changed since 2012 with good cooperation of the Ministry of Economy and other ministries with designated CABs, as well with supervision over the work of these bodies.

In connection with fulfillment of requirements deriving from EU New Approach directives (CE marking), 49% of interviewed economic operators performs CE marking of their products 56% make use of certification bodies from EU, which indicates that these are export-oriented economic entities. Obviously almost all companies whose products bear CE mark, seek for services provided by certification (notification) bodies from EU. This applies even in the case that "third party" involvement for conformity assessment is not required e.g. for LVD, EMC and other directives that do not foresee mandatory involvement of the notified bodies.

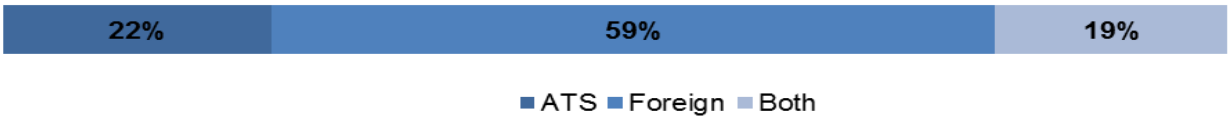
Economic operators, conducting public procurements, showed low level of knowledge related to technical legislation, which was demonstrated in the elaboration of the public procurement documentation. Entrepreneurs, participants in public procurement procedures, as well as representatives of CABs pointed at this.

One of the problems lies in neglecting the obligation of certificates of conformity deriving from technical regulation for certain goods that are purchased. Based on that, Law on public procurements has to be more precise when it comes to technical specifications and acceptance of the proof of quality of product and services of the bidder.

Regarding participation of the economic operators in technical committees of the Institute of Standardization, engaged in the preparation and adoption of standards, the following has been observed: 34% of the interviewed economic operators confirmed that they actively participate in at least one and very often in many technical committees; 31% do not participate at all but is interested in participating; 8% participated in the past but do not participate anymore; 26% didn´t show any interest in participating whatsoever. It can be concluded that there is some space for improvement of the cooperation between economy and ISS.

In the field of product certification, the analysis showed that large number of companies uses the services of foreign CABs, usually notified CABs and smaller number uses local accredited CABs, and small number use services of both.

Graph 11: Certification of products in domestic or foreign CABs



The most frequent reason for choosing services of foreign certification bodies - apart from the mandatory involvement of notified bodies – is related to the use and importance of so called “voluntary” marks such as ENEC, GS, VDE, Keymark etc., which in practice are often a condition for export to certain EU markets.

In addition to these there are other reasons for the use of foreign CABs, such as:

- domestic certificates are not recognized because Serbian CABs cannot be notified bodies before signing ACAA or Serbia’s EU membership;
- image of foreign CABs;

The request of foreign companies that their partners from the Republic of Serbia perform certification of their products abroad;

- lack of testing capacities in Serbia;
- special requirements of the foreign buyers.

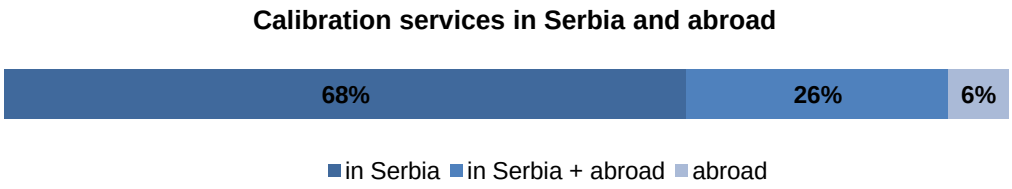
Nevertheless, there are many reasons for taking advantage of certification services of domestic certification bodies, especially after signing EA MLA agreement, such as:

- growing acceptance of Serbian certificates by foreign clients;
- enhancing of image of domestic CABs and their participation in bilateral and international product certification schemes;
- lower certification costs;
- geographical availability of CABs and no language barrier regarding countries in the region.

All these reasons could be an advantage to domestic accredited CABs and they can increase their competitiveness both in the region and in the EU, especially after the signing of the ACCA agreements or accession of the Republic of Serbia to the EU.

Regarding measuring instruments used by the industry, analysis indicated that majority of economic operators calibrate their measuring instruments exclusively in domestic laboratories (68%) and only 6% in laboratories abroad, shown in the graph No. 12.

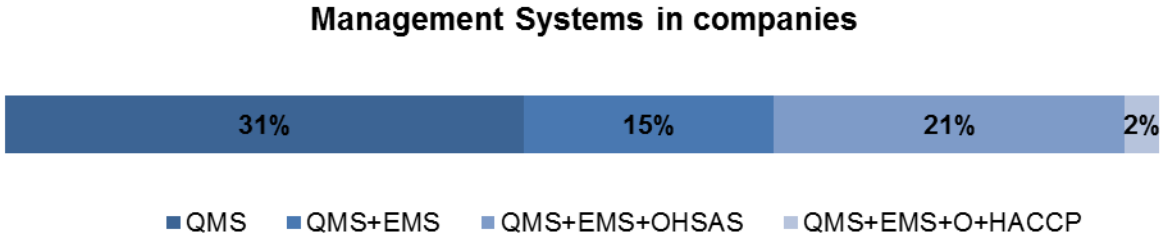
Graph 12: Calibration services in Serbia and abroad



Majority of interviewed companies reported that they were faced with numerous problems until 2010. With implementation of the Law on Metrology and large number of bylaws started and quality calibration service has visibly been improved. In order to enhance its implementation, further education of the economic operators and awareness raising regarding importance of calibration and metrology as such is required.

In the field of Management System Certification (MS), analysis indicated that the majority of economic operators (69%) has some of the **certified management systems** (31% has QMS; 15% has QMS and EMS; 21% has QMS, EMS, OHSAS; 2% has QMS, EMS, HACCP). Besides that, a large number of economic operators that have one or more certified management systems plan to implement some other or an integrated management system. Among those that currently have no certified management system, a great number didn´t perform re-certification due to the high costs.

Graph 13: Management Systems in companies



However, certification of QMS has been only “formally” applied, and only a few economic operators take advantage of QMS for any real improvement of their business. One of the reasons for formal application of QMS is that some regulations require establishment of QMS in certain industries, and that is the only motive for certification. Those economic operators who really implement their QMS, do not find it difficult to adjust to new (harmonized) standards and legal framework.

Besides mentioned analysis, in identifying industry needs, difficulties in the field of QI are taken into account and were pointed out by economic operators in the analysis presented by the

Foreign Investors Council [4]. This council which represents economic operators that have invested almost 17 billion of Euros until 2012 and employ over 88.000 people with direct participation of 16,54% in Serbian GPD, presented the following conclusions:

- Weak participation of experts from economy which would voluntarily work on elaboration of Serbian standards through harmonization of European "EN" standards. Due to the lack of financial and adequate human resources, ISS tends to adopt standards in English language, which is a serious problem for the majority of Serbian companies;
- Lack of commitment of ministries in charge for harmonization of technical regulation and lack of capacities and willingness for speeding up the process of harmonization with EU regulation, especially "Old Approach" directives, is still a problem;

- Lack of awareness on economic justification of compliance with standards as well as on importance of accreditation;
- Lack of capacities in Serbia for assessing conformity with regulations and standards in certain fields. For this reason, companies have to engage a foreign accredited conformity assessment body which causes unnecessary costs for industry.

[4] Source: Suggestions for improvement of Serbian business environment, the White Book for 2012

4. STRATEGIC ORIENTATION OF THE QI DEVELOPMENT

4.1. Vision and mission

Vision: highly developed, balanced, efficient, effective and internationally recognized Serbian QI system, which is a strong support to the competitiveness of the domestic economy and whose key players are regional leaders in the areas of metrology, standardization, accreditation and conformity assessment.

Mission: Serbian quality infrastructure system, professionally and timely responding to demands of economy, enables trade without unnecessary technical barriers, ensures that safe and quality products are placed on the market, ensures high level of consumer health protection and safety and increases competitiveness of Serbian products on national and international markets and furthers the overall economic development of the Republic of Serbia.

4.2 Strategic QI development goals

4.2.1. General goals

I To ensure preconditions for free movement of goods without creating unnecessary barriers to trade, fully in line with the principles and regulations of the common European market and the WTO/TBT agreement;

II To achieve high level of development of key elements of QI: metrology, standardization, accreditation and conformity assessment, that comply with European and international rules and which are recognized by the relevant European and international organizations;

III To achieve full and efficient implementation of legal and institutional QI framework;

IV To ensure high level of consumer health protection and safety, protection of property, protection of environment and other public interest;

V To enhance competitiveness of economy and industry innovations, as well as development of socially responsible management and society in general.

4.2.2. Specific goals

4.2.2.1. Metrology

In the field of metrology, strategic orientation is for DMDM to be leading and internationally recognized national metrology institution in the region that provides all the necessary metrological services in Serbia and participates in the developmental and innovative projects in the areas of measurement, which will improve quality of life of the citizens, economy and sustainable development.

In accordance with that, DMDM's strategic role is to ensure the proper functioning of the metrology system in Serbia, in order to provide accurate, reliable and honest measurements, whose purpose is to contribute to the prosperity, improving the quality of life of citizens and increasing the competitiveness of the economy.

For achieving general strategic QI objectives, in the field of metrology following specific objectives are set:

1. Improvement of the characteristics of existing and development of new national measurement standards in line with the needs of all interested parties in Serbia;
2. Ensuring traceability over national measurement standards of the Republic of Serbia to international measurement standards of SI units, for all interested stakeholders;
3. Improvement of research capacities in the field of metrology, as well as calibration and measurement capabilities that are recognized at international level with active participation in European metrology research and innovation programs;
4. Establishment and supervision over the work of holders of national etalons for the specific areas of measurement for which there are no national etalons in DMDM, and in accordance with the needs of the Republic of Serbia;
5. Continuous harmonization of the Serbian legislation in the field of legal metrology with EU legislation and practices;
6. Strengthening of DMDM capacities to perform conformity assessment of measurements with the prescribed requirements, as designated and future notified body to ensure access to the European market;
7. Effective implementation of market surveillance for measuring instruments and control of pre-packaged products in order to protect consumers, based on European principles, as well as the effective implementation of supervision over the use of legal units of measurements and monitoring of professional work of authorized and designated bodies.

***Goal 1**: Improvement of the characteristics of existing and development of new national measurement standards in line with the needs of all interested parties in Serbia*

In order to achieve this goal, following measures and actions are necessary:

- Reassess realistic metrology related needs of all stakeholders in Serbia and determine fields of measuring which need to be developed or improved and to define fields in which new national measurement standards need to be developed;
- Enhance characteristics and extend the spectrum of measuring possibilities in accordance with needs identified;
- develop new national measurement standards in accordance with identified needs;
- Establish new calibration and measurement possibilities to ensure the traceability of measurements in the fields of chemistry, medicine, environmental protection, energy and food safety;
- To determine fields of measurements for which there is no wider economic or social interest for DMDM to keep, maintain and improve national etalons but can be performed by other subjects in coordination and supervision of DMDM

***Goal 2:** Ensuring traceability, over national measurement standards of the Republic of Serbia to international measurement standards of SI units, for all interested stakeholders*;

In order to achieve this goal, following measures and actions are necessary:

- Continuation of DMDM participation in relevant key and supplementary comparisons and prepare new possibilities for measurement and calibration for publishing in the database of the International Bureau of Weights and Measures in specific areas of measurement, in accordance with the needs;

- Establishment of technical committees for the exchange of know-how and information with calibration laboratories to increase the quality of these laboratories;

- Enabling DMDM for fulfillment of SRPS ISO/IEC 17043 requirements, as a provider for the organization and conducting of inter-laboratory comparisons in accordance with the needs of stakeholders.

Goal 3: *Improvement of research capacities in the field of metrology, as well as calibration and measurement capabilities that are recognized at international level with active participation in European metrology research and innovation programs;*

In order to achieve this goal, following measures and actions are necessary:

- Provide participation in European and other metrology developmental and innovation projects (**e.g.** EMPIR program) in order to establish and improve research capacities in the field of energy efficiency, environmental protection, food industry and creation of innovative products.
- Provide necessary support for participation in these projects and the establishment of research and developmental capacities.

Goal 4.*: Establishment and supervision over the work of holders of national etalons for the specific areas of measurement for which there are no national etalons in DMDM, and in accordance with the needs of the Republic of Serbia;*

In order to achieve this goal, following measures and actions are necessary:

- To determine fields in which DMDM has not kept and maintained national measurement standards, and for which there are institutions in the Republic of Serbia that have the capabilities to maintain and improve them;
- Appoint institutes, or holders of national measurement standards for specific fields of measurements
- Organize surveillance on holders of national measurement standards, by DMDM.

Goal 5*: Continuous harmonization of the Serbian legislation and practices in the field of legal metrology with EU legislation and practices*

In order to achieve this goal, following measures and actions are necessary:

- DMDM shall actively take part in Working groups of European Cooperation in Legal Metrology (WELMEC) and working groups and committees of European Commission for measuring instruments;
- adopt WELMEC Guides for implementation of metrology related directives (MID, NAWI and Pre-packed products) and application of those Guides for more efficient application of directives;
- Provide technical and human capacities in DMDM for carrying out conformity assessment activities for the implementation of the Rulebook on non-automatic weighing instruments and the Rulebook on measurements, i.e. timely transition from type approval and verification of measures to established conformity assessment procedures of these measures
- Make the appropriate changes and amendments of Law on Metrology to ensure that DMDM performs verification of measures in particularly sensitive areas which are of great importance for safety and consumer protection, control and traffic safety, etc;
- Align the organizational structure of DMDM, and in particular the jurisdiction of organizational units in accordance with the amendments to the Law on Metrology.

Goal 6: *Strengthening of DMDM capacities as Designated and Notified Body in future for conformity assessment of measuring instruments, to ensure access to the European market*

In order to achieve this goal, following measures and actions are necessary:

- Building of human resource and technical capacities of the DMDM for performing conformity assessment of certain measuring instruments with requirements prescribed;
- DMDM shall prepare for notification towards European Commission as notified body for conformity assessment of measuring instruments with requirements prescribed, which are primarily produced in Serbia especially in line with modules B and D (type testing and production quality warranty), which are expected to be most interesting for the majority of domestic producers;
- To provide the conditions and required resources for certain tests and implementation of the relevant harmonized standards and normative documents for the implementation of the Rulebook on non-automatic weighing instruments and the Rulebook on measuring instruments;

Goal 7*: Effective implementation of market surveillance for measuring instruments and control of pre-packaged products in order to protect consumers, which is based on European principles, as well as the effective implementation of supervision over the use of legal units of measurements and monitoring of professional work of authorized and designated bodies.*

In order to achieve this goal, following measures and actions are necessary:

- Continuous modernization of technical equipment, improvement of human resource capacities for surveillance activities including change of qualification structure in regional units of DMDM, in order to ensure that only measuring instruments and pre-packaged products that meet the established requirements are placed on the market;
- Develop and use specialized software and data base for surveillance and other activities related to surveillance which are performed by DMDM
- To use risk assessment methodology in planning and conduction of surveillance
- To establish appropriate procedures for surveillance of measuring instruments which are covered by non-automatic weighing instruments and measuring instruments rulebooks, as well as the procedures for surveillance on *pre-packed products*, in accordance with European principles;
- To strengthen cooperation with other market surveillance authorities and consumer protection organizations on planning and conduction of surveillance;
- strengthen cooperation and exchange of information with authorized conformity assessment bodies;
- Continuous review of procedures for surveillance of the authorized bodies for verification of measuring instruments and designated conformity assessment bodies, in order to increase or maintain the level of efficiency.

4.2.2.2. Standardization

The strategic orientation in the field of standardization is for ISS to be recognized at the international, European and sub-regional level as a national standards body which manages the Serbian national standardization system in a way that is fully compatible with the practice followed by EU members and other modern democracies.

The strategic role of the Institute is that, within an efficient and effective national system of standardization, with its competence, professionalism and excellent publications and services, timely meet the needs of all stakeholders.

For achieving general strategic QI objectives, in the field of standardisation following specific objectives are set:

1. Achieve and obtain full membership in the relevant international and European organizations for standardization and ensure adequate participation in all these organizations, both at working and policy levels;
2. Improve awareness of all stakeholders and the general public concerning the importance of standardization and the benefits of applying standards in practice;
3. Increase the active participation of interested parties, especially SMEs in the work of commissions for standards adoption;
4. Assuring translation of prioritized EU standards into Serbian;
5. Introducing new services and increase of efficiency in service delivery by ISS.

Goal 1: *Achieve and obtain full membership in the relevant international and European organizations for standardization and ensure adequate participation in all these organizations, both at working and policy levels*

In order to achieve this goal, following actions and activities are necessary:

- To make changes of the Law on Standardization with the purpose of harmonization with EU Regulation 1025/2012 of European Parliament and Council from October 25th, 2012 on European standardisation;
- To make changes of Decision on Foundation and other documents and to reorganize ISS in line with changed Law on Standardization
- Periodically redefine the number and the structure of commissions in line with priorities of economy and society in general, in order to assure participation of all stakeholders and their efficient performance, as well as effective and efficient work of committees
- Improve ICT technology in ISS in line with requirements for becoming and obtaining full membership in European standardization organizations;
- Assure continuous improvement of ISS human resource capacities for active participation in the work of European and international standard organizations
- Continuously work on training as more as possible external experts – committee members, who will be able to participate in the work of technical working groups (committees, subcommittees and working groups) of European and international standardization organizations;
- Establishment of marketing unit, preparation and implementation of the marketing plan for continuous implementation of activities on attracting all stakeholders, especially small and medium enterprises in the Republic of Serbia to cooperate with the ISS, in order to fully exploit all the advantages of ifull membership and to increase Serbia's contribution to and influence in international and European standardization organizations;
- Provide the conditions for ISS, in addition to revenues from the budget of the Republic of Serbia, to realize and increase its own income from stable alternative sources of funding.

Goal 2: *Improve awareness on the part of all stakeholders and the general public concerning the importance of standardization and the benefits of applying standards in practice*

In order to achieve this goal, following measures and actions are necessary:

- Continuously performing promotional activities related to importance and role of standardization, through holding seminars and similar information events, as well as in the press and electronic media;

- adjust the content of the internet portal of ISS to the needs of all stakeholders

- organize educational seminars on requirements and advantages of application of standards in certain fields.

Goal 3: *Increase the active participation of interested parties, especially SMEs in the work of commissions for standards adoption*

In order to achieve this goal, following measures and actions are necessary:

- perform activities to inform interested parties about the benefits of participation in the standard setting process, through seminars, round tables, printed and electronic publications, as well as strengthening cooperation with economic and sectoral associations;

- Continuously perform activities to increase the number of members in ISS Standards Committees;

- Periodically organize trainings for members of the Standards Committees to learn about the processes, activities and rules of standardization at national, European and international level;

- Prepare a package of measures/benefits for SMEs to enable access to standards and participation in the process of standard elaboration.

Goal 4: *Assuring translation of prioritized EU standards into Serbian*

In order to achieve this goal, following measures and actions are necessary:

- Define criteria for identification of priority standards which should be translated into Serbian (based on the requirements and plans of legislators, demands of legal entities, demands for standards, etc.);

- Strengthen the ISS capacity for translation of standards and continuously educate employees;
- Develop and improve electronic databases of technical terms for the purposes of translating standards;
- Encourage interested stakeholders to translate required standards with their own resources and to submit these translated standards to ISS;
- Provide projects of technical support for the translation of standards
- Establish financing through the budget planning of Republic of Serbia and ensure sustainable financing from alternative sources to cover the costs of standard translation.

Goal 5: *Introducing new services and increase of efficiency in service delivery by ISS*

In order to achieve this goal, following measures and actions are necessary:

- Change the Law on Standardization, Document on Founding and Statute of ISS
- Establish new organizational units;
- Permanently improve all internal processes and procedures
- Strengthening the ISS capacities and developing of conditions for the provision of certification of service of management system certification
- Develop a national mark for conformity of products, processes and services with Serbian standards as a kind of voluntary certification with Serbian standards, adopt rules for its application;
- Continuously conduct promotional activities for usage of Serbian mark of conformity;
- Continuously train human resources for providing consultancy services (technical and professional assistance) for public and private sector regarding standards application and other activities in the field of standardization;
- Continuously improve marketing programs and promotional capacities of ISS including electronic information.

4.2.2.3. Accreditation

In the field of accreditation, strategic orientation is that ATS as internationally acknowledged and leading accreditation body in the region provides all necessary accreditation service according to industry demand.

According to this, strategic role of ATS is to assure confidence in competence in results of Serbian conformity assessment bodies.

In order to achieve general QI system related goals, following specific goals are set in the field of accreditation:

1. Improvement of accreditation system in Serbia including ATS scope extension in line with needs of industry, conformity assessment bodies and state authorities;
2. Maintain signatory status of the agreements on the recognition of equivalence of accreditation systems (EA MLA, ILAC MRA и IAF MLA) and successfully extend scope of internationally recognised activities;
3. Awareness raising of all stakeholders on transparency and importance of accreditation.

Goal 1: *Improvement of accreditation system in Serbia including ATS scope extension in line with needs of industry, conformity assessment bodies and state authorities;*

In order to achieve this goal, following measures and actions are necessary:

- Strengthen the competence of ATS employees by increasing the number of employees who have relevant expertise and experience that is necessary for the performance of accreditation in line with the requirements of the relevant standards and international documents, as well as through further education of ATS employees for certain areas of accreditation;

- improve knowledge and provide continuous training for external assessors and technical experts, as well as employees in ATS, for new types and areas of accreditation, to meet the needs of the economy and state administration bodies;
    - Improving the qualifications of assessors, including annual trainings can be achieved with revision of ATS procedures. Accreditation bodies normally can adjust the procedures, when the need arises (eg. E-trainings over the Internet may not constitute proof of certification bodies on conducted annual training of assessors);
    - Continuously review and improve the ATS management system in accordance with the requirements of relevant standards, regulations and documents of international organizations for accreditation;
- improve the cooperation with stakeholders, especially with state administrative authorities;
- Signing of corresponding memorandums of cooperation with regulatory bodies which adopt regulation, regarding application of those regulations;
- Improve ICT technology and optimize its utilization

Goal 2: *Maintain signatory status of the agreements on the recognition of equivalence of accreditation systems (EA MLA, ILAC MRA и IAF MLA) and successfully extend scope of internationally recognised activities;*

In order to achieve this goal, following measures and actions are necessary:

- Performing in line with the best international practice and continuous improvement of internal processes and procedures and adapting of management system with EA, ILAC и IAF recommendations and procedures;
- Actively participate in the work of relevant international and European organizations for accreditation and contributing to harmonization of practices between accreditation bodies and creation of accreditation policy;
- Through improvement of cooperation with other accreditation bodies, contribute to cross-border procedures implementation;
- Performing of all necessary activities in order to assure international recognition of equivalence of Serbian accreditation in new fields;
- Assuring of a stable and independent source of financing, which is one of the requirements for full membership in European and international organizations for accreditation (Regulation 765/2008/EC).

Goal 3: *Awareness raising of all stakeholders on transparency and importance of accreditation;*

In order to achieve this goal, following measures and actions are necessary:

- continuously perform promotional activities on importance and role of accreditation in the press and electronic media;
- Organize and conduct educational seminars on requirements and advantages of accreditation in certain fields of accreditation;
- Organize presentations to state authorities which adopt technical regulation, about the role and importance of accreditation as the most adequate and efficient method for determining of competence of CABs.

4.2.2.4. Conformity assessment

Strategic orientation of Serbia regarding conformity assessment is that there is a sufficient number of competent CABs, offering services that in an efficient manner meet the needs of the economy.

In order to achieve general goals of QI system in the field of conformity assessment, specific goal are defined:

1. Increase the level of competence and resources of CABs enabling them to perform conformity assessment activities in all areas, putting special emphasis on the needs of the market and development of the local economy, as well as encouraging regional development and export growth.
2. Increased number of CABs that prove their competence through accreditation in relevant areas of conformity assessment.
3. Strengthening the Serbian CABs so they become regional leaders in specific areas of conformity assessment.
4. Strengthening the capacity of authorities and organizations responsible for the preparation and adoption of technical regulations or authorities and institutions responsible for determining if CABs are qualified to implement the suggested conformity assessment procedures, i.e. ensuring the application of best practices of the EU and the WTO, particularly regarding stipulated technical requirements and the monitoring of the implementation.
5. Signing the Agreement on Conformity Assessment and Acceptance of industrial products between the EU and the Republic of Serbia (ACAA), only if a sectorial analysis identifies that the signing of such an agreement is of great importance for Serbian economy.

Goal 1: *Increase the level of competence and resources of CABs enabling them to perform conformity assessment activities in all areas, putting special emphasis on the needs of the market and development of the local economy, as well as encouraging regional development and export growth.*

In order to meet this goal, the activities below are required:

- encourage CABs in strengthening the organizational, technical, technological and human resource capacities, all in order to meet the requirements of the domestic and regional markets;
- help CABs specialize in conformity assessment of selected product groups according to the requirements of the relevant technical regulations, all in line with the needs of the market and the economy, and in collaboration with all stakeholders (business entities, regulators, market surveillance authorities…);
- organize trainings for CABs employees explaining the importance of the product being in compliance with technical regulations and standards, as well as explaining the requirements from sectoral point of view;
- encourage CABs to conduct proper analysis and process the statistic data for the purpose of defining market needs and the needs of the economy;

- help CABs improve their own quality management system, focusing on management and marketing skills, help them improve communication with the clients and develop other business activities, all this in order to better position themselves on the market and increase competitiveness;
- organize trainings on the importance of the stipulated level of product conformity with technical regulations and implemented standards for persons preparing technical specifications in public procurement procedures.

***Goal 2**: Increased number of CABs that prove their competence through accreditation in relevant areas of conformity assessment.*

In order to meet this goal, the activities below are required:

- promote the importance of the accreditation in the field of conformity assessment of the product in line with the technical regulations transposing the European New Approach Directives, as the most important element of the notification of designated CABs to the European Commission;
- promote the importance of accreditation as an essential prerequisite for the CAB, primarily designated CAB, to test the products both for the economy and for the purposes of market surveillance, especially when it comes to the application of the safeguard clause;
- strengthen the capacity of CAB to expand their scope of accreditation in accordance with the requirements of regulations and market demand;
- Amend the Law on Public Procurement in the part related to the technical specifications for products, emphasizing the obligation to obtain certificates of conformity issued by the CAB whose competence was confirmed by accreditation and / or other relevant body;
- Improve transparency in the field of management systems certification, in order to better inform customers and to prevent unethical practices, through the establishment of an electronic register of all accredited certification bodies, including representative offices or branches of foreign certification bodies that provide services on the territory of the Republic of Serbia, accredited by the rules of Serbian or cross-border accreditation body;
- Encourage CAB to form an on-line database of issued certificates of conformity, in both the regulated and unregulated field;
- Encourage specialization of the management systems assessors.

***Goal 3**: Strengthening the Serbian CABs so they become regional leaders in specific areas of conformity assessment.*

To achieve this goal it is necessary to implement the following measures and activities, which are reflected in encouraging:

- CABs to meet the requirements for membership in as many international certification schemes as possible (ENEC, CB, CCA EMC);
- CABs to strengthen the organizational, technical, technological and human resource capacities in order to meet the requirements of international and regional markets
- testing laboratories to be accredited and to participate in programs for proficiency testing (PT schemes), through organizing appropriate trainings and consulting for the implementation of ISO 17043 and the organization and implementation of the PT scheme at regional level;

- integration of the national associations (for laboratories, certification bodies, inspection bodies, etc.) into the appropriate international professional associations (eg, Eurolab and Eurochem), in order to improve their services of quality testing and certification, deepen their cooperation and create good business practices, as well as to establish effective cooperation with legislators, ATS-TV, ISS, DMDM-TV etc.

***Goal 4**: Strengthening the capacity of authorities and organizations responsible for the preparation and adoption of technical regulations or authorities and institutions responsible for determining if CABs are qualified to implement the suggested conformity assessment procedures, i.e. ensuring the application of best practices of the EU and the WTO, particularly regarding stipulated technical requirements and the monitoring of the implementation.*

To achieve this goal it is necessary to implement the following measures and activities:

- Strengthen the capacities of state authorities and regulatory bodies adopting technical regulations, with the improvement of existing and/or education of the new organizational units that will be responsible for the preparation and implementation of technical regulations, including units for determination of qualification of CABs for the implementation of stipulated conformity assessment procedures;
- Ensure that the organizational units in the responsible authorities in charge of technical regulations will be comprised of lawyers and experts from the fields that regulate the technical regulation;
- Strengthening the professional capacities of the organizational units responsible for the preparation and development of technical regulations, through appropriate trainings and education;
- Strengthening the professional capacities of the organizational units responsible for the preparation and development of technical regulations for notification of its legislation according to the WTO and EU rules, as well as the analysis and preparation of comments on drafts/ proposals of notified foreign technical regulations, with the active participation of business entities and their associations;
- Continue with IPA support programs and bilateral donors on the development, updating and implementation of technical legislation, especially in terms on strengthening of specialized knowledge in state authorities regarding transposition of EU legislation in this area;
- Institutionalize and strengthen the coordinating role of the Ministry responsible for technical regulations and conformity assessment in relation to the responsible entities for technical regulations, customs authorities and market surveillance, in order to ensure balanced and timely harmonization with European regulations and continuous review of national technical regulations that will not create unnecessary technical barriers to trade;
- Provide a mechanism for cooperation between state authorities responsible for adoption of technical regulations (transposing EU technical legislation in the domestic legal system) with industry, academic institutions, NGOs and other stakeholders. This cooperation should aim at creating a broad base of experts who will be able to provide their expertise in various fields to strengthen and accelerate the process of harmonization and implementation of legislation within the first negotiating chapter (free movement of goods) and to contribute to the efficient and rational negotiations with the EU in order to achieve the highest possible degree of protection of Serbian economic interests;
- Ensure that state authorities responsible for the adoption of technical regulations from the first negotiating chapter participate as observers, and later as full members of the various committees and working bodies in the European Commission, in which harmonized regulations are set. The aim of this kind of participation is to ensure that the Republic of Serbia is timely informed about the changes and innovations in the European technical legislation, in order to inform domestic

economic entities and their associations as well as to protect interests of the Serbian economy as a whole;

- Prepare and implement the Action plan referring to the national technical rules and administrative measures for trading of products in a non-harmonized area. Action plan should define the role and obligations of competent ministries to perform an analysis of these rules and measures in accordance with the results of the analysis, proposed deadlines and measures necessary for complete conformity with articles 34-36 TFEU;
- Establish a system of continual review of all current technical regulations and ensure that national technical regulations are systematically managed in order to eliminate or prevent the negative technical barriers to trade;
- Provide a legal basis so that technical regulation cannot be adopted without notification procedure of this regulation;
- The establishment of a functional network of contact points for products to provide information on the contents of national technical regulations.

Goal 5: *Signing the Agreement on Conformity Assessment and Acceptance of industrial products between the EU and the Republic of Serbia (ACAA), after a sectorial analysis identifies that the signing of such an agreement is of great importance for Serbian economy.*

To achieve this goal it is necessary to implement the following measures and activities:

- maintain inter-sectoral consultations among regulatory authorities and institutions with the aim of preparing sectoral analysis on the necessity of signing the ACAA;
- organize round tables and seminars informing representatives of the importance and benefits of the ACAA;
- identify groups of products that would demonstrate the benefits of signing the ACAA for the Serbian economy;
- transpose all EU regulations relating to the identified product groups into the Serbian legal system;
- ensure the full implementation of technical regulations transposing the European legislation
- promote the importance of designating CABs as a prerequisite of the European Commission for notification of designated CABs, in order to provide a sufficient number of designated CABs for conformity assessment for identified group of products that are the subject of the ACAA;
- intensify training of designated CABs for future notification to the European Commission;
- increase the number of product checks carried out by market surveillance (sampling and testing) according to the technical regulations which transpose European legislation relevant to the identified product groups;
- amend the by-laws of the Law on technical requirements for products and conformity assessment, related to the CABs and implementation of conformity assessment, i.e. the recognition of foreign certificates of conformity, all in relation to the future role of local CABs as notified bodies.

4.2.2.5. Market surveillance for the purpose of enforcement of technical regulations

In the field of market surveillance strategic commitment is to improve market surveillance in the Republic of Serbia to ensure optimal enforcement of technical regulations.

To achieve this goal it is necessary to implement the following measures and activities:

- Ensure that the different organizational units of market surveillance, which are in charge of specific sectors, dispose of experts qualified for the relevant regulated areas;
- Provide specialization of market surveillance inspectors responsible for safety of products with the requirements from technical regulations, so that the inspector supervises a limited number of technical regulations related to similar product groups;
- Provide continuous training of market inspectors and ensure involvement of market inspectors in the working groups for the development of technical regulations;
- Ensure that inspectors have access to Serbian standards referred in the technical regulations, as well as education regarding the implementation of these standards,
- Encourage the usage of designated and accredited CABs for testing of products for the needs of market surveillance.

5. IMPLEMENTATION AND FINANCING OF THE STRATEGY

Quality infrastructure improvement strategy represents a medium-term strategic document that contains the objectives that will be realized in the next six years. The framework for the implementation of the defined objectives will be specified in annual action plans. Ministry reposnible for the economy will prepare action plan for 2015, three months after adoption of the Strategy. This plan will provide concrete actions for implementation of strategic objectives, deadlines, responsible entities and resources for implementation. Strategy needs to follow the current state regarding the social environment, that is why its relevance and adequacy will be preiodically reviewed in the context of annual action planning exercises and adapted whenever necessary.

For the purposes of implementation of activities envisaged by the action plans and Strategy, funds from the budget will be needed in the amount of the previous annual allocation. In addition, the Ministry in charge of the economy will endeavor to provide continuous support of European and bilateral programs for quality infrastructure for the entire validity period of the Strategy. For this purpose, this strategy will be one of the basic documents that will be used during the programming of foreign assistance in this area.

6. MONITORING THE RESULTS OF STRATEGY IMPLEMENTATION

The ministry in charge of economy will be responsible for monitoring of the results of implementation of annual action plans and strategy in general. For these purposes the Ministry will collect information on the implementation of the activities from all stakeholders involved in the implementation of action plans. In order to be successful in coordination of certain activities from the action plans, the Ministry will organize working meetings with interested parties, on which the information about the experience and the obstacles for the effective implementation of the Action Plan and Strategy will be exchanged. The Ministry will submit an annual report to the Government on the implementation of the Strategy. At the same time, the Ministry may report on the implementation of action plans and Strategy in general, through the web presentation of quality infrastructure sector, so that the general public could be informed about the results achieved in this area.

7. PUBLICATION OF THE STRATEGY

This strategy should be published in the "Official Gazette of the Republic of Serbia".

In Belgrade, dd.mm.2014. year