

ACCREDITATION OF CONFORMITY ASSESMENT BODIES (CAB) IN SERBIA

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Abstract

In the international exchange of goods and services, accreditation gets more and more important. Based on strict adherence to international standards, and determining conformity with them, accreditation became the only authoritative category that proves competence of organizations to perform various services in domestic and international traffic.

Yugoslav Accreditation Body was established 15 years ago, which later grew with the changing regulations in Accreditation Body of Serbia - ATS. By the new Law on Accreditation ATS is registered as an institution, which, as the only in Serbia, entrusted accreditation business.

ATS last year signed the EA MLA agreement on mutual recognition for accreditation of laboratories for testing and calibration, medical laboratories, inspection bodies and certification bodies for certifying products. Last year it also signed an agreement with ILAC MRA for field testing, calibration and inspection.

Accreditation is mentioned directly or indirectly in almost all laws and regulations governing quality and safety of products and services. In Serbia there are 546 accredited CAB in different areas and different scope of accreditation.

This year, under the auspices of the Serbian Chamber of Commerce, is formed Association of accredited CAB, as ATS partner, strengthening infrastructure of conformity assessment, support the accreditation system, impact of the adoption and harmonization of national legislation, and to promote its own services.

Problems in the work of ATS are particularly in evaluating the organizations, which is primarily related to the harmonization of the criteria for assessing. Stricter assessment criteria in order to be in global trends, un-

dertake work to strengthen the education of all participants in the process of accreditation.

Key words: Accreditation, CAB, ATS.

1. Introduction

In the international exchange of goods and services, accreditation gets more and more important. Based on strict adherence to international standards, and determining conformity with them, accreditation became the only authoritative category that proves competence of organizations to perform various services in domestic and international traffic. Accreditation ensures the free movement of goods, removing technical barriers to international trade and constantly improve the quality of goods and services.

Ministry of Economy and Regional Development (now the Ministry of Finance and Economy) is created the basis for establishing of the new modern quality infrastructure system in Serbia [1]. Preparing, and then in the Serbian parliament adopting, four key laws - Technical Requirements for Products and Conformity Assessment [2], Standardization [3], Accreditation [4] and Metrology [5] - it is opened the way towards meeting international requirements for the free movement of goods and services, bearing in mind, first of all, their quality.

Accredited conformity assessment bodies is one of the most important link of quality infrastructure in management of security and safety products (and services) that are placed on the market in Serbia, as well as, exported from the country.

Given in the subconscious all aspects of quality infrastructure, in this paper we will deal only with accredited conformity assessment bodies

2. Accreditation - Legislation

Accreditation is a process conducted by a national accreditation body upon which it determines and verifies that a specific organisation meets the requirements necessary to perform certain conformity assessment activities laid down in relevant international standards and that it is competent to perform the said activities [4].

In Serbia accreditation is conducted by the Accreditation Body of Serbia - ATS, founded by the Republic of Serbia as the sole institution for performing accreditation activities in accordance with the Law on Accreditation [4].

Administrative organs of the Accreditation Body of Serbia are the Management Board, Director and Supervisory Board with clear defined tasks. As a professional body in the ATS act Accreditation Council and technical committees for specific areas of accreditation. Members of accreditation Council are appointed and replaced by the Management Board. Renowned experts and scientists from fields relevant to the performance of activities falling within the competences of the ATS are chosen to become the members of the Council as representatives of interested parties. Technical committees are technical bodies providing expertise required for certain fields of accreditation. Technical committees as standing or ad hoc bodies are established by the Director as per the proposal of the Council [6, 7].

The purpose of accreditation is to determine competence of conformity assessment bodies to perform activities for testing, calibration, inspection, certification of products, certification of management systems and certification of persons. It was subsequently included accreditation of medical laboratories.

Establishment and maintenance of a competent, impartial and independent accreditation system is a strategic task which ATS should fulfill, at any moment, that users for services of accredited conformity assessment bodies (CABs), citizens, consumers and businesses in Serbia should have confidence in the services provided by accredited laboratories, control and certification bodies.

In the field of accreditation, the impartiality rule requires that the accreditation body has to be impartial in making decisions on accreditation. This means that the ATS shall not have any conflict of interest with the body applying for accreditation and that the ATS shall not be subject to any kind of pressure that might be of political, commercial, financial, etc. nature in order not to jeopardise its impartiality.

ATS applies itself to promote the importance and recognition of the role of accreditation, and to properly perform its tasks in order to safeguard the general interest by being the highest authoritative level of

control of conformity assessment services delivered in both voluntary (market driven) and mandatory (law regulated) spheres.

As such, accreditation must be carried out under the following conditions:

- with recognised mandate from the government at national level
- in such a fashion as to completely observe independence and impartiality requirements
- with full accountability towards all interested parties, with no party being a predominant majority preference
- an accreditation body shall be a non-profit institution in order to avoid any competition with accredited conformity assessment bodies.

When granting accreditation, the ATS endeavours to safeguard the interests of all parties involved, whereby the attention shall be paid to the independence of the assessors when deploying an assessment team.

ATS strives to carry out the wishes of its clients as long as it does not affect the assessment, by deploying various forms of communication to assert its role amongst clients and to successfully anticipate the needs of the market for the new services and information.

The ATS's success depends on well organized internal structure, particularly emphasise the importance of good business communication, clear decision-making structure within the ATS and clearly defined tasks, competences and responsibilities.

Participation in appropriate training and education leads to the increased level of competence of assessors and technical experts, while the ATS continually monitors and evaluates the competence levels of its assessors and technical experts during assessments, i.e. by being part of the assessment team through announced or unannounced witnessing, accreditation decision-making process, and on feedback from assessed conformity assessment bodies, opinions and possible complaints. Such capacity building measures in case of permanent employees and external assessors and experts involved, and maintenance of an appropriate level of competence is essential to the accreditation decision-making process. Thus, the ATS upholds and safeguards its integrity as the trust-oriented institution in accordance with its slogan - "trust in competence".

2.1 Chronology of accreditation in Serbia

The Yugoslav Accreditation Body (JUAT), later to become the Accreditation Body of Serbia (ATS), was founded in 1998 by means of the Decree on the Establishment of the Yugoslav Accreditation Body - JUAT [6].

In the period between 1998 and 2000 JUAT performed its accreditation activities as a collegial public administration body of the Federal Republic of Yugoslavia within the Federal Ministry of Development, Science and Environment. On 28th June 2000, this collegial body made its first decision on accreditation.

From 2000 to 2003, JUAT was a separate organisation, a collegial body detached from the Ministry, and from June 2003 to June 2006, it was a constituent part of the Ministry of Internal Economic Affairs of Serbia & Montenegro. It changed its name thereafter to the Accreditation Board of Serbia & Montenegro [8].

By means of the 2006 Act on Establishment enacted by the Government of the Republic of Serbia [9] ATS acquired the legal personality, and status of independent and non-profit body in accordance with the Law on Accreditation (10) the implementation of which commenced on 01.01.2006.

After the new Law on Accreditation [4] has entered into force ATS was registered as an institution, while a law governing public administration services was applied in case of the ATS establishment, set-up, status and activities-related issues. ATS is the sole accreditation body in the Republic of Serbia that was delegated the performance of the accreditation activities by means of the Law on Accreditation.

The Decision on Amendments of the Act on Establishment of the Accreditation Body of Serbia [6] entered into force on 24th February 2011, whereby the existing English version of the name of the national accreditation body "Accreditation Board of Serbia" was changed into "Accreditation Body of Serbia".

2.2 Accreditation in the world

In EU Member States and EFTA countries have established a European network of national accreditation bodies commonly known as the European co-operation for Accreditation (EA) enabling the competence of laboratories, inspection and certification bodies to be assessed against the criteria laid down in international standards and procedures. EA is a non-profit organisation that is given a prime role to define, harmonise and build consistency in accreditation as a service with the aim to reduce barriers to trade and to contribute to protecting health and safety.

Furthermore, EA was established as the official European accreditation infrastructure in accordance with Regulation (EC) No. 765/2008 of the European Parliament and of the Council [11] establishing a legal framework for accreditation throughout Europe. This Regulation provides that each Member State shall appoint a single national accreditation body that the government shall entrust with the operation of accreditation as a public

authority activity and grant it formal recognition in accordance with the requirements of international standards in both the private and public sector.

In addition to EA as the most important regional organisation acting as the official European accreditation infrastructure, there are international organisations governing accreditation globally - in the field of laboratory, inspection and certification body accreditation. These are the International Laboratory Accreditation Cooperation - ILAC and International Accreditation Forum - IAF.

2.3 International agreements

The task of accreditation bodies as stipulated in the agreements signed with the European co-operation for Accreditation (EA MLA), International Laboratory Accreditation Cooperation (ILAC MRA) and International Accreditation Forum (IAF MLA) is to promote a system of accreditation and equivalence of accreditation systems. These agreements are signed on the basis of the detailed evaluation of procedures and criteria of the accreditation body (peer evaluation) in question, whereas the peer evaluation is conducted by a team of experts in specific fields of accreditation. A uniform approach used to determine competence of conformity assessment bodies worldwide enables countries to sign mutual agreements on the basis of evaluation and recognition of accreditation systems and to reduce the number of unnecessary product controls in international trade and to create conditions for the free movement of people, goods, services and capital.

EA MLA is an agreement signed between the EA accreditation body members to recognise the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports across Europe (EA Region). In addition to the aforementioned multilateral agreement a country may sign a bilateral agreement (BLA) with the EA where the difference between the MLA (multilateral) and BLA (bilateral) agreements is essentially a non-existent one, except that the MLA agreement is signed by a country which is a full EA member, and BLA is signed by an associate member. All obligations of the countries that signed these agreements remain the same.

Enforcement of EA multilateral/bilateral agreements is carried out through peer evaluation conducted by evaluators from other accreditation bodies. The purpose of these rigorous on-site evaluations is to verify the signatories' continuing conformity with the internationally accepted criteria. Accreditation bodies are evaluated against the international standard - ISO/IEC 17011 [12], Regulation No 765/2008 [10], other related criteria such as application documents from EA, ILAC or IAF and applicable criteria on behalf of European or

National Regulators and industrial schemes. The MLA process is overseen by the European Commission, the EA Advisory Board and the national authorities.

After signing the EA MLA, products or services of suppliers need no longer to be tested, certified, or inspected when placed on the market in other countries. Thus, this agreement constitutes a basis for the upgrade of international trade and global market, whereby costs are reduced and benefits for the industry and consumers are increased.

With a strong commitment, after "peer" evaluation, conducted during 2011th, on 24th May 2012 ATS is signed the EA MLA agreement to the following areas of accreditation [13, 14]:

- Testing laboratories;
- Medical laboratories;
- Calibration laboratories;
- Inspection bodies and
- Certification bodies providing certification of products.

ATS is a signatory to the ILAC MRA (Mutual Recognition Agreement) for testing and calibration, and on 25th October 2012 ILAC MRA agreement was signed for the field of inspection [15]. It is, also, a signatory to the IAF MLA (Multilateral Recognition Agreement) in the field of product certification on the basis of the said multilateral agreement with EA [15].

The benefits of signed multilateral agreement have all interested parties [16]:

- accredited conformity assessment bodies;
- accreditation bodies;
- regulatory and trade officials;
- importers, exporters and consumers;
- the national infrastructure.

In addition to international multilateral agreements, accreditation bodies can conclude agreements on bilateral cooperation in the field of accreditation. ATS has concluded agreements on bilateral cooperation with the following bodies in the region [13]:

- Hungarian Accreditation Body,
- Institute for Accreditation of Bosnia and Herzegovina
- Accreditation Body of Montenegro
- Institute for Accreditation of the Republic of Macedonia and
- Croatian Accreditation Agency.

2.4 Accreditation in Serbia

Accreditation is mentioned directly or indirectly in almost all laws and other regulations in Serbia which determines the quality and safety of production and trade, as well as the provision of services.

In Serbia there are 503 accredited conformity assessment bodies in different areas and different scope of accreditation [13]:

Accreditation for	Reference	N° bodies
Testing laboratories	[17]	300
Calibration laboratories	[17]	53
Medical laboratories	[18]	8
Certification bodies operating certification of products	[19]	14
Inspection bodies	[20]	106
Certification bodies operating certification QMS	[21]	7
Certification bodies operating certification EMS	[21]	6
Certification bodies operating certification FSMS	[21]	4
Certification bodies operating certification OHSAS	[21]	5

In January 2013th ATS was awarded the first accreditation to the body for certification of personnel [22], according the standard ISO / IEC 17024: 2005 [23], given that the decision of the General Assembly of the IAF established a transition period of three years to implement a new version of the same standard issued in 2012th [24]. Institute for Standardization has released a new version of the standard, and standard from 2005 th was withdrawn.

It must be pointed out, as the above example shown, that on successful work of ATS, significantly influenced the Institute for Standardization of Serbia, which was promptly published standards immediately after their original publication.

The accreditation process is conducted in accordance with the standards and rules set forth by international organizations. Successfully passed exams on the occasion of peer evaluation, and the signing of agreements with international organizations, obligates ATS to constantly raise the level of work and tightening to meet the requirements during the assesment. Full-time employees in ATS, participating in conferences at home and abroad constantly improve their knowledge.

In the process of accreditation, ATS engages external assessors and technical experts who have appropriate education, recognized skills and experience needed in the assessing areas. At the end of 2012. there were 252 registered assessors, between them there were 89 leading assessors, 148 technical assessors and 120 technical experts [13].

However, regardless of the conditions that meet externally engaged assessors, with work in different organizations, with different experiences in the field of accreditation, with different quality systems solutions in documents of their organizations, show different criteria for evaluation. This especially applies to the criteria in the areas of uncertainty, validation (verification), conducting internal quality control, participation in PT schemes. Recognizing these problems and to ensure consistency in the evaluation criteria ATS conducts continuous training of assessors organizing different courses, according to the type and area of accreditation or for the implementation of an appropriate standard.

In addition, the constant improvement of the applied standards, the tightening of the evaluation criteria, and to be in trend with the global aims, has to be done to strengthen the education of all participants in the process of accreditation from assessors till the direct performers of activities from the scope of accreditation in accredited CABs.

2.5 Association of the accredited conformity assessment bodies

Given the situation in the market and recognizing the everyday problems faced by, a group of accredited and nominated conformity assessment bodies, initiated establishment an association of accredited conformity assessment bodies.

According to above mentioned, and given that the Chamber of Commerce of Serbia through its organizational structure, legal authorization, institutional capacities, membership in international associations and organizations, work in partnership with local government authorities and institutions, as well as, great number of members from all sectors of the economy, has the highest organizational, technical, informational resources for the functioning of such an association it was decided to form it within the Serbian Chamber of Commerce.

This initiative has been forwarded to the Assembly of the Serbian Chamber of Commerce, and, at the meeting held on 28.03.2013. were adopted amendments to the Statute of the Chamber, in accordance with the initiative, and thus created the legal framework for the establishment of the association.

Forming Accredited Conformity Assessment Bodies within the Serbian Chamber system will allow direct communication of members, their exchange of experiences, the harmonisation of working processes. In this way, the profession will preserve their identity and be able to perform business in full compliance with international standards.

Associated Accredited conformity assessment bodies may uniquely respond, identify root causes of problems and propose measures in critical situations in the country and participate in the formulation of development policy in many areas. All of the above mentioned is a function of the real consideration of the justification of organized association and activity in the framework of the Serbian Chamber of Commerce as a viable functional community of Accredited bodies in Serbia.

Associating will enable integration into international professional associations (Eurochem, Eurolab) in order to strengthen the trust and improve the quality of service, reliability and competence.

Expected benefits for members of the association is reflected in the greater availability of information, interaction and exchange and improve the knowledge and experience, cooperation with the Accreditation Body of Serbia in order to improve the accreditation system to raise awareness of the importance of accreditation to improve competitiveness and strengthen confidence in the quality of products and services Serbian market.

The objectives of The Association of Accredited Conformity Assessment Bodies, as determined by the initiative group are [25]:

- Strengthening infrastructure for conformity assessment of goods and products (and services) with the aim that only a secure and safe products may be placed on the market;
- Improving the quality of services of accredited conformity assessment bodies in order to meet customer needs;
- Promotion of best practices and establish a network for cooperation at national and international level;
- More efficient establishment of inter-laboratory comparisons in order to ensure confidence in the quality of test results in accredited organizations;
- Advancement of cooperation in order to ensure traceability;
- Supporting and strengthening the system of accreditation;
- The impact on the adoption of regulations;
- Improving the knowledge of employees;
- Development of recommendations for better implementation of the relevant requirements;

- Contribution to the harmonization of national legislation with international regulations in the field of quality infrastructure and technical legislation.

Initiative group has adopted the working principles of the association:

- Promoting best practice in respect the highest standards of service quality and ethical principles;
- Publicly talking on values of the independent evaluation of a preventive action, process monitoring, product, service and environmental protection;
- Openness to all stakeholders in order to improve the professional and ethical standards;
- Publicity of work.

At the end of June 2013., on the plenary meeting held at the Serbian Chamber of Commerce, is formed Committee Association accredited conformity assessment bodies, which has 27 members, respecting proportional representation according to the areas of accreditation, with the corrective factors including regional and professional representatives [26]. Key activities of the Committee are defined as:

- Identifying interests and alignment of interests with other stakeholders and with other associations and committees in the Chamber of Commerce of Serbia;
- Representing of agreed interests on the national and international level;

initiating and participating in the adoption of legislation, technical regulations and standards;

participation in the harmonization of technical legislation with the European Union;

- Adoption of ethical standards;
- Adoption of strategies of public communication and involvement in communication with the public;
- Increasing awareness about the importance of conformity assessment of processes, products and services;
- Planning of activities and participation in the implementation of activities;
- Adoption of rules on the operation of the association;
- Provision of access to information for members of the Association and other interested parties.

3. Conclusions

- Accreditation of conformity assessment bodies in Serbia has deep roots. Fifteen years have passed since the first act of accreditation was adopted. The legal framework quality infrastructure is completed,

and accreditation is an important part of that. Favorable regulatory environment, significant efforts employed in the Accreditation body of Serbia or external assessors who participate in the assessment procedures, have led to the signing of agreements with international organizations (EA, ILAC, IAF), and accreditation system in Serbia has been recognized as a very good, which allows that the certificate is valid beyond the borders of Serbia. The final step in completing the accreditation system is the formation of the Association of accredited conformity assessment bodies in the framework of Serbian Chamber of Commerce.

- All these activities should be reflected in the creation of an enabling economic system, for inclusion in the international division of labor and provide greater Serbian presence in the international trade of goods and services.

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