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STANDARDS IN FUNCTION OF QUALITY OF PRODUCTS

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ABSTRACT

Quality infrastructure with its components ensures compliance of products and services with the mandatory requirements, protection of the interests of consumers and businesses and contributes to the maintaining of the quality of products and services. Quality infrastructure promotes export, competitiveness and innovation. Conformity assessment helps to ensure certainty that products and services are delivered on their promises, in other words: conformity assessment builds trust. Typical activities of conformity assessment are: taking samples, laboratory testing, inspection, assessment, verification and provision of declaration, certification, and combinations thereof.

Key words: accreditation, conformity assessment, inter-laboratory comparison, Proficiency Testing_PT schemes

1. INTRODUCTION

Technical standards define and dictate the level of safety of the facilities, which depends on their category. Typically, these values are higher for public facilities, and lower for individual buildings. However, technical standards also define the criteria that building products must meet in order to be suitable for their purpose, to ensure that the facilities meet the basic requirements that are set out in the Regulation - Construction Products Regulation - CPR.

All products individually in a different manner contribute to the safety of the facility - some are more important (for example, supporting elements, roof, fire protection doors, etc.), while others are not so important (interior doors, covered panels, etc.). CPR includes five different systems for assessment and verification of constancy of the properties of building products (Assessment and Verification of Constancy of Performance - AVCP). All systems are a combination of tasks that are performed by the manufacturer and by third bodies or conformity assessment bodies.

Quality infrastructure is of vital importance and represents an integral part of the economy and is one of the foundations of national, regional and international trade.

The infrastructure quality system includes: standardization, metrology, accreditation, conformity assessment and market inspection.

Conformity assessment helps to ensure that products and services are delivered on their promises, in other words, conformity assessment builds trust. Conformity assessment ensures that the consumers select products on the basis of reports from the tests and certificates issued by specialized laboratories and certification bodies. Typical activities of conformity assessment are: taking samples, laboratory testing, inspection, assessment, verification and provision of declaration, certification, and combinations thereof.

2. CONFORMITY ASSESSMENT BODIES REGARDING CONSTRUCTION PRODUCTS REGULATION_CPR

The European parliament and the Council on 9 March 2011 adopted Regulation No 305/2011-(Construction Products Regulation_CPR), which is mandatory and directly applicable from 1 July 2013 in all European countries. CRP repeals Council Directive 89/106/EEC-CPD.
The Regulation includes provisions for conformity assessment that are included in the process of conformity, and which will be authorized to carry out tasks for third parties in the process of assessment and verification of constancy of properties (AVCP) under this Regulation.

2.1. Body for laboratory testing – MKC EN ISO/IEC 17025

Laboratory testing is one of the conformity assessment activities. Quality assurance of laboratory results is accomplished by accreditation of the laboratories according to the standard MKC EN ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories. Laboratory accreditation bodies use MKC EN ISO/IEC 17025, specifically to assess factors relevant to the laboratory technical competence, including the: (1) technical competency of personnel; (2) validity and suitability of test methods; (3) traceability of measurements and calibrations according to national standards; (4) suitability, calibration and maintenance of testing equipment; (5) sampling, handling and transportation of test samples and (6) quality assurance of test and calibration data. This standard consists of two modules: (1) laboratory management requirements (clause 4 from the standard); (2) technical requirements for competence of laboratories (clause 5 from the standard). Regarding clause 5.9 of ISO/IEC 17025, an important way of meeting the requirements in the area of quality assurance of laboratory results is proficiency testing (comparative testing).
Officially, by the end of 2010, for the improvement of the quality of test and calibration results, two sets of international documents were used: for internal quality assurance (IQA) – MKC EN ISO/IEC 17025 and for external quality assurance (EQA) – ISO/IEC Guide 43 and ILAC G13. Since the end of 2010, for the purpose of external quality assurance, the international standard MKC EN ISO/IEC 17043 – Conformity assessment, General requirements for proficiency testing – has been used. Proficiency testing (comparative testing) is an important way of meeting the requirements of ISO/IEC 17025 (clause 5.9) in the area of quality assurance of laboratory results. It is also mandated by accreditation bodies that laboratories participate in proficiency testing programs for all types of analyses undertaken in that laboratory, when suitable programs exist. Proficiency testing involves a group of laboratories or analysts performing the same analyses on the same samples and they obtain comparing results. The key requirements of such comparisons are that the samples are homogenous and stable, and also that the set of samples that are analyzed are appropriate to test and display similarities and differences in results.

2.2. Certification bodies for products – MKC EN ISO/IEC 17065

Product certification is a tool that provides assurance that the product conforms to the specific requirements set out in standards and standardization documents. Although this standard applies to the bodies operating as a third party, many of these provisions can be used also with bodies operating as first and second parties, in their internal procedures for assessing the conformity of products.
Until recently, the ISO/IEC Guide 65:1996 – General requirements for product certification bodies, allowed these certificates to be implemented in a competent and fair manner. Now a new standard promises to take this process to the next level. The text of the Guide has been completely revised, proven parts are retained and improved where needed and as a result of the revision a new standard was released: ISO/IEC 17065:2012 – Conformity assessment – Requirements for bodies certifying products, processes and services. The new standard clearly indicates that the certification of products can be applied both to processes and services. The new informative annex (Annex A) shows how the standard can be interpreted specifically for processes and services. The new annex identifies the principles that govern the product certification bodies as well as their activities. These principles inspire confidence in the certification process. Keywords are impartiality, competence, confidentiality and openness, responding to complaints and appeals, and responsibility. Many of the requirements of

MKC EN ISO/IEC 17065 are clarified and based on feedback from many years of experience and formal interpretation of ISO/IEC Guide 65.
The concept that is often mentioned in the MKC EN ISO/IEC 17065 is certification schemes. They include all specific requirements, rules and procedures relating to a product (or a group of products) in order for them to be certified.

3. METHODOLOGICAL RESEARCH

Empirical survey of the view-points of management and employees in laboratories was conducted. The survey was conducted on 21 samples and the paper analyzes only the results of accredited testing laboratories. The survey was conducted only in accredited laboratories for the reasons that at the moment only two certification bodies are accredited for construction products, out of which one in June and the other body in December 2016.
The aim of this research is to: (1) gain a clear understanding of the overall state of laboratories in terms of their accreditation and participation in inter-laboratory comparisons; (2) define the benefits of their accreditation and participation in inter-laboratory comparisons, (3) locate the problems and obstacles they are facing in the implementation of the relevant requirements specified in the standard MKC EN ISO/IEC 17025 and (4) assessment of the economic justification of the accreditation.
The implementation of the standards is not an easy process, although it contributes to the effective and efficient functioning of laboratories and the achievement of desired results.

3.1. Description of the questionnaire elements

The questionnaire was designed in a way to cover issues of implementation of the standard MKC EN ISO/IEC 17025 and MKC EN ISO/IEC 17043. At the same time, the questionnaire includes questions about the management and organization of work (implemented MKC EN ISO 9001), as well as financial viability, and suggestions and recommendations for improvement in the organization of work in modern market conditions. A survey of the view-points of the representatives of the management of laboratories was conducted in order to get the opinion of managers and employees engaged in laboratory testing. This survey was carried out during the period from November 2012 to March 2015 in the territory of the Republic of Macedonia.
Using statistical methods in the analysis of responses and creating diagrams and charts, a range of view-points were received, which reflect the real situation in the country in terms of accredited laboratories and their participation in inter-laboratory comparisons.
The first part of the questionnaire is related to point 4 of the standard MKC EN ISO/IEC 17025. It refers to measurement of the improvement level in the process related to management of the laboratory: (1) document management; (2) customer satisfaction; (3) human resource management; (4) processes management.
The second part of the questionnaire is related to point 5 of the standard MKC EN ISO/IEC 17025 – competence of the laboratory. It refers to measurement of the degree of: (1) participation in inter-laboratory comparisons; (2) participation in PT schemes; (3) the establishment and development of PT schemes; (4) accredited PT schemes.

4. ANALYSIS OF THE RESULTS

According to the official data of the Institute for Accreditation of the Republic of Macedonia (IARM), in the Republic of Macedonia there are 142*[1] accredited bodies for conformity assessment of 110*[2] organizations. Overview of accredited bodies for conformity assessment is given in Table 1.

[1] Condition as of June 2015
[2] Condition as of June 2015

Table 1. *Overview of accredited bodies for conformity assessment*

Conformity assessment bodies		N	Total
Laboratories (MKC EN ISO/IEC 17025/ MKC ISO 15189)	testing	66	75
	calibration	8	
	medical laboratories	1	
Certification bodies (MKC EN ISO/IEC 17021/ MKC EN ISO/IEC 17065)	quality management systems	1	3
	products	2	
Inspection bodies (MKC EN ISO/IEC 17020)		64	64

From a total of 66 testing laboratories, most common are laboratories in the field of chemistry (43,9 %), while according to the type of testing products/materials, the greatest number of laboratories are in the environment sector and samples from the environment (30,3 %). Of the total number of testing laboratories, 6 laboratories are operating in the area of construction sector, which is a representation of 9,1 % according to the type of product/material – building products, materials and structures. In agreement with the above mentioned, building products, materials and structures are ranked as the third most common type of products/materials for testing.

Overview of the percentage share of laboratories according to the type of product is given in Table 2, while the representation of accredited laboratories according to the type of product in the construction sector is presented in Table 3.

Table 2. *Representation of laboratories according to types of products/materials for testing*

Types of products/materials for testing	Biological samples	Construction products, materials and structures	Electrical products and equipment	Industrial materials and products	Environment and samples from the environment	Food	Fuels, lubricants and industrial oils	Furniture	Textile and leather	Objects of general use	Medical products	Agricultural products	Others
N	4	6	1	2	20	14	2	1	1	1	2	5	3
% of represen -tation	6, 1	9,1	1,5	3,0	30,3	21,2	3,0	1,5	1,5	1,5	3,0	7,5	4,5

Table 3. *Representation of laboratories according to types of products/materials for testing in construction sector*

Types of products/ materials for testing	Joinery and wood products	Concrete	Stone and aggregate	Stone and soil	Masonry unit	Ceramics	Refractory materials and products	Bituminous mixtures	Thermal insulation materials	Structures	Construction Products	Cement
N	1	3	2	4	1	1	0	2	0	3	1	2

All these standards represent indirect support to the legal regulations, i.e. the Law on construction products. The harmonized standards, to which the law refers, provide methods and criteria for assessing the functionality of the construction products in relation to its basic characteristics.

With this example the authors wish to acknowledge that implementation of standards is not an easy process. It is evident that laboratories define the area and the methods to be accredited according to the existence of relevant legal framework. Therefore, if the legislation defines certain features of the product that should be tested according to standard methods, then the laboratories include only these methods in the scope of accreditation. One gets the impression that the link legislator – manufacturer is the determining factor in the defining of the scope of accreditation, while the demands of client/business associate – manufacturer, are pushed into the background.

However, in order to ensure a quality product, to ensure reliable test results, satisfaction of customer requirements, as well as strengthen the market position, laboratories engage in the process of accreditation. This process carries certain benefits as identified by the laboratories from the construction sector and as shown in Figure 1.

Most of the laboratories (18 %) said that they had noticed visible improvements in the management of documents, improved competence of personnel and better defined methods and working procedures.

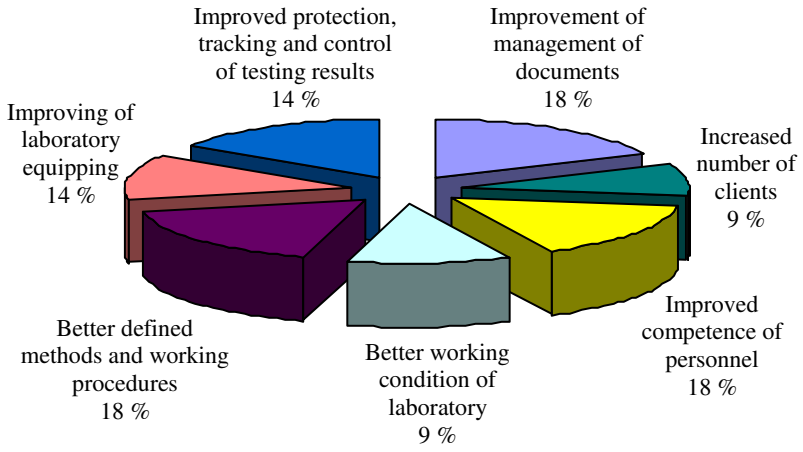

Figure 1. *Improvements in the laboratories after accreditation*

Accreditation of laboratories, in clause 5.9 of the standard MKS EN ISO/IEC 17025, sets out the requirements for participation in inter-laboratory comparisons. In accordance with the conducted research, laboratories in the construction sector 100 % meet these requirements. In the construction sector 4 laboratories (80 %) participate in a total of 21 PT schemes. It is important to point out that 3 laboratories in the construction sector (60 %) have established and developed a total of 10 non-accredited PT schemes.

5. STANDARDIZATION WITHIN THE SCOPE OF WOOD BASED PANEL

Unfortunately, in the Republic of Macedonia there are no accredited laboratory tests in the field of wood based panels. If we want to provide quality and safety products on the market, we must understand that only the standards will allow it. The standards with the methods of testing define and imply the degree of safety.

The crucial harmonized standard in this area is standard MKC EN 13986:2006+A1:2015 –Wood-based panels for use in construction – Characteristics, evaluation of conformity and marking.

However, we should not neglect the following standards that refer to the general conditions, definitions and classifications of the products, as well as the standards that have been discussed before, and these are the standards that refer to the test methods. These standards are given in Table 4.

Table 4. *Standards within the scope of the European Committee CEN TC 112 – Wood based panel*

Reference	Title
МКС EN 319:2011	Particleboards and fibreboards - Determination of tensile strength perpendicular to the plane of the board
МКС EN 317:2011	Particleboards and fibreboards - Determination of swelling in thickness after immersion in water
МКС EN 382-1:2011	Fibreboards - Determination of surface absorption - Part 1: Test method for dry process fibreboards
МКС EN 633:2011	Cement-bonded particleboards - Definition and classification
МКС EN 1128:2011	Cement-bonded particleboards - Determination of hard body impact resistance
МКС EN 1328:2011	Cement bonded particleboards - Determination of frost resistance
МКС EN 634-1:2010	Cement-bonded particleboards - Specification - Part 1: General requirements
МКС EN 314-2:2011	Plywood - Bonding quality - Part 2: Requirements
МКС EN 635-1:2011	Plywood - Classification by surface appearance - Part 1: General
МКС EN 635-2:2011	Plywood - Classification by surface appearance - Part 2: Hardwood
МКС EN 635-3:2011	Plywood - Classification by surface appearance - Part 3: Softwood
МКС EN 382-2:2011	Fibreboards - Determination of surface absorption - Part 2: Test method for hardboards
МКС EN 1087-1:2011	Particleboards - Determination of moisture resistance - Part 1: Boil test
МКС EN 12775:2011	Solid wood panels - Classification and terminology
МКС EN 13017-1:2011	Solid wood panels - Classification by surface appearance - Part 1: Softwood
МКС EN 13017-2:2011	Solid wood panels - Classification by surface appearance - Part 2: Hardwood
МКС EN 635-5:2011	Plywood - Classification by surface appearance - Part 5: Methods for measuring and expressing characteristics and defects
МКС EN 313-1:2011	Plywood - Classification and terminology - Part 1: Classification
МКС EN 313-2:2011	Plywood - Classification and terminology - Part 2: Terminology
МКС EN 315:2011	Plywood - Tolerances for dimensions
МКС EN 314-1:2011	Plywood - Bonding quality - Part 1: Test methods
МКТИ CR 213:2011	Particleboards - Determination of formaldehyde emission under specified conditions - Method called: formaldehyde emission method
МКС EN 14755:2011	Extruded particleboards - Specifications
МКС EN 300:2010	Oriented Strand Boards (OSB) - Definitions, classification and specifications
МКС EN 622-1:2010	Fibreboards - Specifications - Part 1: General requirements
МКС EN 309:2011	Particleboards - Definition and classification
МКС EN 622-2:2010	Fibreboards - Specifications - Part 2: Requirements for hardboards
МКС EN 622-3:2010	Fibreboards - Specifications - Part 3: Requirements for medium boards
МКС EN 13986:2006	Wood-based panels for use in construction - Characteristics, evaluation of conformity and marking
МКС EN 634-2:2010	Cement-bonded particleboards - Specifications - Part 2: Requirements for OPC bonded particleboards for use in dry, humid and external conditions
МКС EN 622-2:2010/AC:2010	Fibreboards - Specifications - Part 2: Requirements for hardboards
МКТС CEN/TS 635-4:2011	Plywood - Classification by surface appearance - Part 4: Parameters of ability for finishing, guideline
МКТС CEN/TS 1099:2011	Plywood - Biological durability - Guidance for the assessment of plywood for use in different use classes
МКС EN 13354:2011	Solid wood panels (SWP) - Bonding quality - Test method

MKC EN 636:2012	Plywood - Specifications
MKC EN 622-4:2012	Fibreboards - Specifications - Part 4: Requirements for softboards
MKC EN 622-5:2010	Fibreboards - Specifications - Part 5: Requirements for dry process boards (MDF)
MKC EN 14279+A1:2011	Laminated Veneer Lumber (LVL) - Definitions, classification and specifications
MKC EN 14272:2012	Plywood - Calculation method for some mechanical properties
MKC EN 312:2011	Particleboards - Specifications
MKC EN 320:2012	Particleboards and fibreboards - Determination of resistance to axial withdrawal of screws
MKTC CEN/TS 16526:2013	Sandwich boards for furniture (SWB-F) - Factory made products - Definition, classification and test methods for determination of performance characteristics
MKC EN 13353+A1:2012	Solid wood panels (SWP) - Requirements

6. CONCLUSION

The accreditation process in the Republic of Macedonia began in 2006, while the first laboratory in the field of civil engineering was accredited in 2008. Unofficial data shows that in the Republic of Macedonia the total number of laboratories by far exceeds the number of accredited laboratories and hence arises the question: why is this the case?

The accreditation process includes the costs of hiring consultants and evaluators, more time for preparation of accreditation, limited human resources, and when to this is added the cost of maintaining accreditation, use of reference materials and calibration of instruments, it becomes clear that accreditation is an expensive process. Laboratories should find the optimal way to simultaneously meet all these requirements. Service prices are low, so is the number of clients, and it does not increase. Therefore, there is a large number of accredited laboratories from the public sector, which are financially supported by the government, while industry is represented by only 13 %. On the market there is still unfair competition, so that it is impossible to increase the prices of services of accredited laboratories. Research has shown that laboratories within their scope of accreditation include mainly the methods that support the Regulation, which supports the fact that manufacturers are aiming at meeting the basic minimum legal requirements for product quality and safety. It is more than obvious that the methods for testing the characteristics of products that do not support the Regulation are accredited to the minimum number.

From the above mentioned it can be concluded that the price of services, unfair competition, low awareness of the standards, the high cost of accreditation, represent a limiting factor for the laboratories to initiate the accreditation process.

Despite all the problems, there are laboratories and certification bodies which had made the first steps and showed high performance and good results.

Developing countries should create an environment for successful integration of their economies in the European and international markets. The process of harmonization of the Macedonian legislation with the legislation of the European Union is currently underway and the authorities should bear in mind that without accredited laboratories, without certification bodies, without participation in inter-laboratory comparisons, the risk involved in the placement of products on the European market can only be increased.

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