

# **QUALITY AND BUSINESS EXCELLENCE**

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Ivana Mijatović, Biljana Tošić, Milan Jovanović

### **ACQUIRING THE KNOWLEDGE ABOUT STANDARDS IN THE DIGITAL ERA – CASE OF SMEs OPERATING IN SERBIA**

Milan Dronjak

### **SMART STANDARDIZATION**

Dragana Rošulj, Gordana Pejović

### **MODEL FOR APPLICATION OF THE BUSINESS CONTINUITY MANAGEMENT SYSTEM IN HIGHER EDUCATION INSTITUTIONS**

Đorđe Lazić, Tamara Mitrović

### **INFLUENCE OF SOME ASPECTS OF DISTANCE LEARNING ON QUALITY OF STUDYING**

Jovan Stokić, Aleksa Sekulović, Mladen Đurić

### **OVERVIEW AND FUTURE OF QUALITY MANAGEMENT CONCEPTS IN ADDITIONAL AIRLINE SERVICES IMPROVEMENT**

Ana Čobrenović, Milica Rajković, Mladen Đurić

### **RISK MANAGEMENT INTEGRATION THROUGH ISO 9001:2015, ISO/IEC 27001:2013 AND ISO 22301:2012 STANDARD REQUIREMENTS**

Dejan Hadži-Milosavljević, Jovan Filipović

### **THE SOFTWARE IMPLEMENTATION OF THE PROTECTION MEASURES OF INFORMATION IN THE BANKING INFORMATION SYSTEM**

Gordana Pejović, Biljana Tošić, Jelena Ruso

### **BENCHMARKING AS THE QUALITY MANAGEMENT TOOL FOR THE EXCELLENCE ASSESSMENT OF MEDICINES REGULATORY AUTHORITIES IN EUROPE**

Tamara Jakovljević

### **QUALITY OF LIFE AND DIGITAL TRANSFORMATION IN HEALTHCARE**

Nedeljko Živković, Maja Glogovac, Ana Horvat

### **PUBLIC ADMINISTRATION QUALITY DETERMINED BY CUSTOMER-RELATED CAF MODEL**

## ACQUIRING THE KNOWLEDGE ABOUT STANDARDS IN THE DIGITAL ERA – CASE OF SMES OPERATING IN SERBIA

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**Abstract:** *In European Union only 0.2% and in Serbia only 0.6% of all enterprises are not Small and Medium Enterprises (SMEs). Improving capabilities of SMEs to be competitive in the global market in a knowledge economy is an important, specific and complex task. How can SMEs be helped to acquire needed information and knowledge? What sources of knowledge in the digital era are most suitable to SMEs? The aim of this paper is to explore main factors which affect SMEs' choice of a dominant source for acquiring information and the knowledge about standards. The questionnaire survey research method was used to seek the response from representatives of 130 SMEs operating in Serbia. Our findings indicate four sources – relevant Web sites, service of consultants, customers and business and other partners. The larger SMEs with the long tradition in business will have more chances to use Websites as the primary source for gaining knowledge about standards. Domestic SMEs shape their decisions to hire consultants services predominantly because of the negative perception of standards. The usage of customer inputs as the dominant source for gaining information and transfer of knowledge about standards are influenced by SMEs' experience in business (years) and negative perception of benefits of standards. In the digital era, SMEs still suffer from lack of resources or capabilities to use the WEB and the Internet for acquiring information and knowledge about standards.*

**Keywords:** Standards, SMEs, Certification, Knowledge, Digital Era

### 1. INTRODUCTION

In the European Union, 99.8% of all enterprises are SMEs and about 23 million SMEs provide around 75 million jobs accounting for 67% of total employment in a non-financial business sector (European Commission, 2018). According to the Annual Report on European SMEs (2017), SMEs are a major source of entrepreneurial skills, innovation, and employment. In Serbia, 99.4% of all enterprises are SMEs. SMEs in Serbia contribute a share of roughly 60% of employment and less than 50% of value added, compared with the respective EU averages of 67% and 57%. Micro-firms make a particularly small contribution, providing only 10% of value added, 11 percentage points lower than in the EU (SBA, 2016).

Capabilities of SMEs to be competitive on the global market in a knowledge economy are high in agendas of many actors – governments, international organizations, chambers of commerce, professional and industry associations. In emerging economies, the contribution of SMEs is to drive the development of a knowledge-based economy and on the other side, in developed countries, SMEs support is seen as crucial for the recovery after the global financial crisis (Massaro et al., 2016). However, SMEs are most vulnerable to – lack of information, knowledge, and incentive; skill shortages; limited market power; high dependence on partners; market behavior of competitors and information asymmetry affect them in many ways (La Rocca et al., 2011; Chong et al., 2016). Study of Chong et al. (2016), based on data collected from owners and managers of SMEs, showed that "external knowledge is believed to be an important need by the enterprises". In many cases, the ability of SMEs to acquire new knowledge is dominant prerequisite to develop and sustain competitive advantage.

The aim of this paper is to explore main factors which affect SMEs' choice of a dominant source for acquiring information and the knowledge about standards. In the digital era, it would be logical that the answer can be found on the Web and the Internet. However, information and knowledge about standards, standardization, and related activities might be quite specific. In the next part of this paper, the literature review is given in order to explain needs of SMEs for knowledge about standards, standardization, and certification. Part 3 is dedicated to research methodology (study design, data analysis, and study participants). At the part 4, results of research are given with the summary statistics for discriminant function analysis (DFA). In the part 5, and are given discussion and conclusion remarks.

## 2. LITERATURE REVIEW

According to the European Committee for Electrotechnical Standardization (CENELEC) (2018), a standard is “a document that sets out requirements for a specific item, material, component, system or service or describes, in detail, a particular method or procedure”. A standard can be defined as “an agreed way of doing something” (BSI, 2018). Essentially, standards are base for the functioning of industries on global levels. Not only that standards facilitate the global economy, they are base for the global trade. Standards can help or hinder entrance on specific markets. One of the roles of standards on the global market is to lower an informational asymmetry – fact that producers have much more information than B2B customers and end-users. Standards are commonly accepted benchmarks that transmit information to customers and about a product’s quality and safety characteristics (Nadvi, 2008).

Do you know what is common for DVD, Bluetooth and Wi-Fi? Generally nothing, except that the DVD Forum, the Bluetooth Special Interest Group and the Wi-Fi Alliance are standards development organizations (SDOs). The global economy is shaped, not only by power and competitiveness related to prices, “but increasingly by technological and organizational innovations that are codified in a series of global standards” (Coe and Hess, 2007). Standardization is booming discipline; many organizations develop standards – special agencies of the United Nations, formal standardization development organizations (e.g. ISO, IEC or ITU-T), professional associations (e.g. IEEE), industry associations (e.g. API) and companies. Standards can be very different in their nature. Some of them are generic and applicable to many organizations, no matter their size, area of business or other features. “Product standards include specific designs, technical characteristics, and attributes of a given product, as well as sector-specific technical standards and product safety standards. Such standards are of critical importance, especially to well functioning global production networks without which globally dispersed supply chains could not function” (Nadvi, 2008). Many standards for systems, processes or products define requirements that can be used as a base for certifications.

According to the International Organization for Standardization (ISO), certification is “the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements” (ISO, 2018). There are many specific types of certifications, some of them are provided by first parties (e.g. organizations provide objective evidence that can be used in quality assurance), others by second parties (e.g. B2B consumers), or by third parties (by neutral organizations) (Loconto and Busch, 2010). Nowadays, companies perceive certification as a mechanism to signal credibility, build a reputation and provide objective evidence to their B2B customers, partners or actors in the processes of public procurements. Study of Rillo & Mijatovic, (2016), based on data from 5632 small and large manufacturing and service firms of 26 Eastern European countries, showed positive influence of quality certifications of quality management systems as well as that larger, more experienced companies and companies with good ICT capabilities are more likely to be certified. International certification is more important to the companies from developing countries and it is connected with “building of reputation” (Rillo & Mijatovic, 2016).

Li at al. (2018) argue about signaling effect of certification in innovative SMEs in China, finding many issues related to the strength of SMEs to provide certificates to signal to outside potential capital providers, reducing information asymmetry without increase of cost. In the specific economy of China, same authors underline the role of government as a provider of certification which can send a signal to outside capital providers, reduce information asymmetry and cut cost. Study of Heinz and Guldenberg (2010) concludes that modern technologies and management practices such as quality management and flexible production technologies allow SMEs to simultaneously reduce costs and differentiate products. In that way, SMEs can improve their competitiveness on the global market. Same study findings indicated that SMEs with an ambition to grow have higher growth and profitability which support claims that the attitudes and values of SMEs owners and managers impact development and performance.

One of the myths in standardization is that standards are applicable only to large companies, that implementation of standards can cause high expenses and that SMEs cannot benefit from standards (BSI, 2018). While SMEs may be underrepresented in standard writing groups and their interests may thus not be sufficiently taken into account (CEN/CENELEC, 2018), SMEs can definitely benefit from standardization itself. Standards can help them reduce costs, improve their innovative capacity and enhance their competitiveness (European Commission, 2018). That is why it is important to explore the interests of SMEs as potential users of standards. “Through addressing their needs, the use of standards may be significantly increased. Furthermore, if standards take more account of the SMEs perspective, considerable benefits would accrue to all stakeholders in standardization” (European Commission, 2018).

European non-profit association Small Business Standards (SBS) was established to – represent and defend SMEs interests in standardization at the EU and international level; raise SMEs awareness of the benefits of

standards and get more SMEs involved in the standardization process (European Commission, 2018). The SBS is collaborating with all the European organizations for standardization, such as CEN, CENELEC, and ETSI, national standardization bodies as well as the ISO. Amongst one of its main activities, SBS is committed to "raise the awareness of SMEs interests within the European Standardization System through its cooperation with standardization stakeholders and its representation in committees, working groups and task forces related to standardization" (SBS, 2018). This way, SMEs are "given a voice in the standardization process and are given the opportunity to actively shape the outcome of standards" (SBS, 2018).

Based on experience of South Korea, study of Chung et al. (2011) revealed that transition to the technological frontier is increasingly related to standardization; latecomer countries improve their technological capabilities from mature towards new technologies; and successful technological catch-up is related to abilities of companies to take part in global (ICT) standardization – "... slow progress can be expected, but once a minimum level of capabilities is achieved, a nation pro-active in standards from the beginning may attain higher rates of catch-up near the technology frontier." Knowledge about standardization is important because of the role of standards and standardization in global and knowledge economy –, especially for less developed countries.

The ability of SMEs to acquire new knowledge is dominant prerequisite to develop and sustain competitive advantage. Based on our literature review we found that an information and a knowledge about standards as a base for certification is an important asset of the SMEs, especially in developing countries. In this study, we would like to explore dominant sources for acquiring knowledge about standards. Our research questions are:

RQ 1: What are the main predictors of the usage of the relevant Web sites as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?

RQ 2: What are the main predictors of the usage of the services of consultants as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?

RQ 3: What are the main predictors of the consumers as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?

RQ 4: What are the main predictors of partners and others as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?

### **3. RESEARCH METHODOLOGY**

#### **3.1. Study Design**

In order to find answers for our research questions, a questionnaire survey research method was used to seek a response from representatives from SMEs which operate in Serbia. We used several sources for reaching representatives of SMEs – database of companies of the Chamber of Commerce of Republic of Serbia (publicly available contact and basic information on the website of Chamber of Commerce), LinkedIn profiles of companies and direct e-mail contacts. In order to receive as many as possible responds, we created relatively short and compact questionnaire, taking into account recommendation for defining a questionnaire and a survey design of Czaja and Blair (2005). In order to find out what influence choice of SMEs operating in Serbia, to use predominantly one source for seeking the information and the knowledge about standards, examinees are asked to choose only one dominant source for gaining knowledge. We observed four sources – relevant Web sites, service of consultants, customers and business and other partners (dependent variables, coded as dummy use=1 and no use=0).

#### **3.2. Data Analysis**

For the data analysis and answering our RQs we used descriptive statistics and we conducted a two-group Discriminant Function Analysis (DFA) based on the Wilks' lambda. Interpretation of the DFA is based on discriminant loading because it is less affected by multi co-linearity and more suitable for interpretation in explorative research (Hair et al., 2009). According to the same author, discriminate loadings above  $\pm 0.40$  should be used to identify substantive discriminant (independent) variables even when they are not included in DFA analysis. The Canonical Correlation (CC) coefficient is used to define the percentage of variance in the dependent variable explained by the mutual influence of independent variables. Based on the study of Harlow (2005), the substantial value of canonical correlation is 0.30 or higher, for example, the value of 0.30 corresponding to about 10% of the variance explained.

### 3.3. Study Participants

Questionnaires were sent via LinkedIn and E-mail to 540 companies and we received 143 responds (26.5%), 13 questionnaires being invalid for the reason of not being SMEs or incomplete data and a total of 130 or 24 % questionnaires have been taken into account. Characteristics of the responding companies are presented in Table 1.

**Table 1.** Characteristics of Responding SMEs

	Total		Ownership				Ownership2			
	Number	%	Public		Private		Foreign		Domestic	
			Number	%	Number	%	Number	%	Number	%
	130	100	10	7.7	120	92.3	30	23.1	100	76.9
	<b>Industry</b>									
<b>Manufacturing</b>	31	23.8	2	6.5	29	93.5	10	32.3	21	67.7
<b>Service</b>	72	55.4	8	11.1	64	88.9	18	25	54	75
<b>Trade</b>	22	16.9	0	0	22	100	1	4.5	21	95.5
<b>Other</b>	5	3.8	0	0	5	100	1	20	4	80
	<b>Number of employees</b>									
<b>0-10</b>	49	37.7	1	2	48	90	1	2	48	98
<b>11-50</b>	41	31.5	1	2.4	40	97.6	9	22	32	78
<b>50-250</b>	40	30.8	8	20	32	80	20	50	20	50
	<b>Experience in certification of processes or products</b>									
<b>Experience in certification with process and products</b>	42	32.3	6	14.3	36	85.7	14	33.3	28	66.7
<b>Experience in certification with process or products</b>	27	20.8	1	3.7	26	96.3	6	22.2	21	77.8
<b>No experience</b>	61	46.9	3	4.9	58	95.1	10	16.4	51	51

## 4. RESULTS

### 4.1. Reliability Analysis

In order to analyze the reliability of the used items, we used reliability coefficient of Cronbach's alpha. According to Hair et al. (2009), the lower limit for Cronbach's alpha is 0.70, although it may also be decreased to 0.60 in exploratory research. The reliability analysis showed an adequate consistency of the entire scale, wherein it is possible to form a summated scale for: 1) perceived benefits from certification ( $\alpha = 0.807$ ) and 2) perceived reputation benefits of application of standards ( $\alpha = 0.738$ ).

### 4.2. RQ 1: WHAT ARE THE MAIN PREDICTORS OF THE USAGE RELEVANT WEBSITES AS A DOMINANT SOURCE FOR INFORMATION AND KNOWLEDGE ABOUT STANDARDS IN THE CASE OF SMES OPERATING IN SERBIA?

The dominant variable that influences usage of Web sites at observed SMEs, as the dominant source for gaining information and transfer of knowledge about standards, is the number of employees (Table 2). Only variable x2: Experience in business (years) have discriminant loadings higher than 0.4 (0.43) and can be discussed in this results. The larger SMEs with the long tradition in business will have more chances to use Websites as the primary source for gaining knowledge about standards. Values of squared canonical correlations suggested that influence of the number of employees is positive and significant, but it corresponded only about 4% to variation between SMEs that use Web sites and SMEs that do not use Web Sites as the dominant source of knowledge about standards.

**Table 2.** Summary Statistics for Discriminant Function Analysis

Dependent variable	Wilks' Lambda	p	Discriminant loadings (structure correlations)									Canonical correlation
			X1	X2	X3	X4	X5	X6	X7	X8	X9	
Websites	0.967	0.04	<b>1.00</b>	<b>0.43</b>	0.28	0.11	0.12	-0.38	-0.27	0.23	0.09	0.18
Consultants	0.909	0.02	-0.34	-0.06	-0.195	<b>-0.516</b>	<b>-0.70</b>	<b>0.71</b>	-0.07	-0.21	0.19	0.34
Customers	0.924	0.01	0.19	<b>0.70</b>	0.101	<b>-0.440</b>	<b>-0.623</b>	0.04	-0.30	-0.11	-0.02	0.28

Legend: x1 – Number of employees; x2 – Experience in business (years); x3 – Experience with certification of processes or products; x4 – Perceived benefits from certifications; x5 – Perceived benefits from standards;

x6 – Domestic or foreign ownership; x7 – Public or private ownership; x8 – Industry (manufacturing or service and others) and x9 – Connections with other smes in same industry.

#### **4.3. RQ 2: What are the main predictors of the usage of services of consultants as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?**

Variables that have a statistically significant influence on the usage of consultants' services as a dominant source for gaining information and transfer of knowledge about standards are the negative perception of standard and domestic ownership (Table 2). The variables that have discriminant loadings higher than 0.4, but are not included in function, are the negative perception of benefits of certifications perceived benefits from certification. Those results suggest that domestic SMEs shape their decisions on hire consultants services predominantly because of the negative perception of standards and standardization. Values of squared canonical correlations suggested that influence of the negative perception of benefits from standards and domestic ownership is significant, but it corresponded only about 12 % to variation between SMEs that hire consultants and SMEs that do not use services of consultants for the purpose of gaining knowledge about standards.

#### **4.4. RQ 3: What are the main predictors of the consumers as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?**

Variables that have a statistically significant influence on the usage of customer inputs as the dominant source for gaining information and transfer of knowledge about standards are: experience in business (years) and negative perception of benefits of standards (Table 2). The negative perception of certifications has discriminant loadings higher than 0.4 (-0.44). Those results suggest that domestic SMEs are pressured by their B2B customers, trough requirements for standards adoption and second part certifications but SMEs have the negative perception of standards and certification. Values of squared canonical correlations suggested that influence of experience in business, negative perception of benefits from standards and domestic ownership are significant, but it corresponded only about 9 % to variation between SMEs that see customers and SMEs that do not see customers as the dominant source for gaining information and knowledge about standards.

#### **4.5. RQ 4: What are the main predictors of partners and others as a dominant source for information and knowledge about standards in the case of SMEs operating in Serbia?**

Our data analysis failed to find any statistically significant influence of observed dependent variables on the choice of observed SMEs to have business partners and other partners as the dominant source for information and gaining knowledge about standards.

### **5. DISCUSSION AND CONCLUSION**

More than ever before, global and regional initiatives for education about standardization are intensive and actual. The Joint Initiative on Standardization under the Single Market Strategy of European Commission, which started at June 13th, 2016, gives high priority on education about standardization (Action 3) and position of SMEs in standardization in supporting European competitiveness in the global market. The International Cooperation on Education about Standardization (ICES) together with ISO, IEC and ITU organize back to back events for exchanging experience related to education about standardization. University Jiliang from China initiated the establishment of The Universities and Academics Alliance for Standardization Education and membership were accepted globally.

The main intention of this article was to explore key factors which affect SMEs' choice of a dominant source for acquiring the information and the knowledge about standards. In the digital era, SMEs still suffer from lack of resources or capabilities to use the WEB and the Internet for acquiring information and knowledge about standards. Our results showed that observed SMEs operating in Serbia use Websites as the main source for acquiring information and knowledge only if they are larger (medium) and more experienced. In the broader sense, our results agree with findings of the study of Neirotti et al. (2018) that adoption of Information and Communication Technology (ICT) in SMEs "has some peculiarities that may depend on the combined effect of size and competitive environment" and that ICT-based capabilities are more diffused among larger SMEs.

Our results showed that domestic SMEs, due negative perception about standards, use services of consultants for the purpose of gaining knowledge about standards. Two problems that have roots in the

negative perception of standards are already visible in practice – the inability of domestic SMEs for successful technological catch-up and lowering quality and effects of consultants' work. The best consultants cannot help SMEs with negative quality culture and cannot do anything if owners and/or managers have negative perceptions towards standards. Consumers, predominantly B2B consumers, are: choice of a dominant source for acquiring information and the knowledge about standards of experienced SMEs' and negative perception of benefits of standards. Those results might be influenced by requirements of B2B buyers or consumers, who require from their suppliers to fulfill requirements of specific company standards.

Richard Stallman's, scientist and one of the pioneers of free software movement said: "Sharing is good, and with digital technology, sharing is easy" (note 1). However, our research results suggest that more attention should be paid to improve capabilities of SMEs for more active use of digital technologies in order to acquire the knowledge about standards, standardization, and related activities. On the other side, the task of many actors: governments, universities, organizations for standardization, consultants and others is to explore why domestic SMEs are missing a chance to benefit from the implementation of standards due to their lack of abilities to use technology-enhanced learning in the digital era.

## NOTE

<sup>1</sup> The quote was retrieved 12.3.2018. from: [https://www.brainyquote.com/quotes/richard\\_stallman\\_473487](https://www.brainyquote.com/quotes/richard_stallman_473487)  
More about Richard Stallman's work and activism can be found at the [www.stallman.org](http://www.stallman.org).

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## SMART STANDARDIZATION

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**Abstract:** *The third industrial revolution is behind us. We are on the doorstep of a new technological revolution whose key elements are Cyber-Physical Systems and the Internet of Things, and this revolution is known as the Fourth Industrial Revolution. This study was conducted using the methods of analysis and synthesis, in order to explore the meaning of smart standardization and to review its place and role related to the Industrie 4.0. The research was done using relevant academic and scientific books and papers during a four-month period of time. The results of this paper suggest that the smart standardization, at this moment, poses the highest level of social awareness related to the importance of technical integration. The role of standardization supporting the emergence of Industrie 4.0 is discussed. It was concluded that the standardization is ubiquitous and has very important place in the development of Industrie 4.0 model and associated technologies.*

**Keywords:** *Smart standardization, Fourth Industrial Revolution, Smart Factory, CPS, IoT*

### 1. INTRODUCTION

We are living in a very dynamic environment. The world around us is evolving very fast, the production of data and information is so high so we are not aware of changes in many cases. One of things that are happening right now is something that many people call the fourth industrial revolution (Industrie 4.0). Steam power was the main characteristics of The First industrial revolution. The Second was related to electric power. The Third was digital revolution and this Fourth is continuation of previous revolution and comprises of many advanced technologies, mainly focused on the Internet (Hatzakis, 2016, p.1). Now, we have Cyber-Physical Systems (CPS) that represent some kind of smart systems. In the world of CPS, standardization is a must and it should be smart.

The objective of the current study was to explore the meaning of the term "smart standardization" and to see its impact in the modern world that is distinguished by the Fourth industrial revolution. This paper is divided into 5 logical blocks. The first part is the Introduction which announces the topic. The second part introduces terms "smart" and "smart standardization" and it also presents related standardization efforts. Nowadays, term "smart" is used for many things from our daily life. Probably, the first association is smartphones but there are also Smart Cities, Smart Farming, Smart Grids or Smart Factories. In this paper focus is on Smart Factory concept which is described with emphasize on the Internet of Things (IoT), as a base, and this is presented in the third part of the paper. The importance of integration of CPS and IoT in Smart Factory concept as well as the ways for achieving high flexibility and efficiency are very important. The main sections of smart factory are listed, while self-awareness and self-comparison of machines are underlined. IoT technology is explained and the growth of connected things is noticed. Additionally, current reality with dominant concept of digital factory is presented. The importance of standardization is accentuated. Architecture Model for Industry 4.0 (named: RAMI 4.0) is shown as the most important reference standard for Industrie 4.0. Finally, there are discussion and conclusion sections, respectively.

### 2. SMART STANDARDIZATION

The term "smart" has a very broad use, and if we look at dictionary, there can be found about its formal and informal meaning. In formal way, it is some fashionable and upmarket place or some clean, tidy, and well-dressed person or rather bright object and fresh in appearance. In informal meaning, we are speaking about something that has or shows a quick-witted intelligence. If we have a device in our mind, it must be programmed so as to be capable of some independent action (Smart, 2018).

If we look at standardization, NATO defines "smart standardization" as a voluntarily creation of standards, their institutionalization in a Standardization Agreement (STANAG) and making them a habit (Cihangir, 2014, p.1). And, if we try to google the Internet for any formal definition, it will not be found.

Bearing this in mind, we can look at the world of standards. Very often, we can find something „smart“. A good example is ISO 37100 series of standards, which helps communities, including cities to define their sustainability objectives and put strategies in place to achieve them. Behind this series of standards, we can recognize Smart city concept. There are also other standards related to this Smart city concept, as ISO

17742:2015 (Energy efficiency and savings calculation for countries, regions and cities), ISO 39001:2012 (Road traffic safety management systems - Requirements with guidance for use), ISO 24510:2007 (Activities relating to drinking water and wastewater services, Guidelines), ISO/IEC 30182:2017 (Smart city concept model - Guidance for establishing a model for data interoperability) etc. In the last-mentioned standard, it can be found the definition of a smart city as „ an effective integration of physical, digital and human systems in the built environment to deliver a sustainable, prosperous and inclusive future for its citizens”. This ISO/IEC standard referenced a term from the BSI PAS 180 which provides common language about Smart cities in the United Kingdom (BSI, 2014).

Not only cities can be smart, but also farming can be smart. Recently renewed standard for serial data control and communications networks in forestry or agriculture, ISO 11783-1:2017, provides open system interconnect (OSI) for electronic systems in this industry (ISO, 2017). In ISO Focus, it can be found that the AGCO Corporation, American agricultural equipment manufacturer, participates in the development of ISO standards because of their importance to overall company strategy (ISO Focus, 2017, p.9). More specifically, AGCO uses ISO 11783 to connect devices and to exchange data between tractors. As we can suppose, Smart farming concept is behind.

In the energy domain, one of the most often used words is the term Smart Grid. In this case, we have international standard ISO/IEC 30101:2014 which characterizes the requirements for sensor networks to support “smart grid technologies for power generation, distribution, networks, energy storage, load efficiency, control and communications, and associated environmental challenges” (ISO, 2014). As we can see, smart concept is behind, again. Smart Grid can be interpreted as a complex system that is capable to operate at different operation modes, ranging from sensing and actuation to command and control (ISO, 2014).

Nowadays, much more attention is paid to the Smart manufacturing, which is process that is capable to use advanced information and manufacturing technologies in order to improve manufacturing efficiency, enabling at the same time flexibility of physical processes. Smart manufacturing is seen as the next Industrial Revolution or Industry 4.0 (Trade Magazine, 2018). Behind this we can also see the Smart Factory concept. For those who work in this area, it is well known ISO 10303 standard for the computer-interpretable representation and exchange of product manufacturing information or IEC TS 62832 for Digital Factories. We can go even further, and find Smart infrastructure concept, Smart energy concept, Smart transportation concept etc.

### **3. SMART FACTORY CONCEPT**

Presently, one of the most demanding projects is the Factory of the future (known as Smart Factory concept), which is also described in IEC White Paper. There are many local initiatives directed towards creating Smart Factory: Advanced manufacturing (in USA), e-Factory (in Japan), Industrie 4.0 (in Germany) and Intelligent manufacturing (in China). Behind those concepts there is the Smart Manufacturing Leadership Coalition (SMLC) or the Industrial Internet Consortium (IIC) in USA, and industrial associations including VDMA, Bitkom and Zvei in Germany, for example (IEC, 2015, p.25).

It is important to emphasize that there is no unique definition of the term named Smart Factory. This term is used both by specialists from the industry and academic writers (Radziwon&Bilberg, 2014, p.1185). Probably, the optimal definition of Smart Factory for the purpose of this study is that it is as a Factory that “context-aware assists people and machines in execution of their tasks”. In the backward definition, “context-aware” means that the systems running in background (so-called “Calm-systems” and “context-aware applications”) can access to context information (position or status, for example) during processing of tasks (Lucke et al., 2008, p.116). Calm systems, previously mentioned, are the hardware of a Smart Factory with ability to communicate and interact with its environment.

In Smart Factory concept, it is possible to collect, distribute and access to manufacturing relevant information anytime and anywhere. Horizontal and vertical integration of information systems, the assignment of material and flow of information within an enterprise is *condicio sine qua non* for this concept. If we take Industrie 4.0 as example, it includes horizontal integration, through value networks, of data flow among partners, suppliers and customers, and also vertical integration within organization (from development to final product) (Hozdic, 2015, p.29). The vertical integration is referring to Cyber-Physical Systems (CPS) or Internet of Things (IoT). By this type of integration of hierarchical subsystems, it is possible to form flexible and reconfigurable manufacturing system inside a factory. There is an another integration. It is engineering integration from one end to another, which extends through the entire value chain in order to support product customization (Wang et al., 2016).

On the other hand, in the process the Smart Factory concept implementation, smart objects should be combined with big data analytics. Those objects can be reconfigured dynamically in order to achieve high flexibility. Achieving high efficiency via global feedback and coordination can be provided by big data analytics (Wang et al., 2016, p.159). This leads to the profitable and efficient production of products that are tailored to the user needs and in small lots.

There is only one responsibility of the Smart Factory during production of finished products, and that is to process raw materials and semi-finished products. The Smart Factory, as well as any other real today's factory, consists of many subsystems which can be either physical or informational. In today's factories, disruption of the information flow can occur for a variety of reasons. Therefore, it is very difficult to provide the continuity and consistency in those factories. At the same time, there is a flexibility problem of material flow because of reasons related to the fixed production lines (Wang et al., 2016).

Overall framework of smart factories can be divided into three major sections: components, machines and production systems. Smart machines use real-time data from their own components and other machines which brings self-awareness and self-comparison. This enables machines to assess their own performance in order to prevent potential failure and to adjust their settings and performance properly through the knowledge they gained from their working history (Lee, 2015, p.231).

### **3.1. Internet of Things (IoT)**

Some individual authors believe the Internet of Things, wireless sensor networks (WSN), big data, cloud computing, embedded systems, and mobile Internet will be emerging technologies (Wang et al., 2016, p.159) that will make the backbone of the Smart Factory. Currently, IoT turned out to be more powerful.

The Internet of Things can be interpreted as the interconnection of things in real time in purpose of sense and report. According to definition of International Telecommunications Union (ITU), IoT is a "global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies" (ITU-T, 2012, p.1). IoT is also one of the core technologies for the 5G network 5G communications.

Every sensor in a factory and also every actuator is a participant in the IoT. All of them have IP address and are networked. In order to achieve Smart Factory concept, it is needed to develop and make available standardized connectors and connection protocols and allow exchange of information between device and connector without loss (IEC, 2015, p.48).

In ISO FOCUS (2016), it can be found estimation (p.8) from Technology consulting firm Gartner, Inc. that 6.4 billion connected things will be in use worldwide by end of 2016, which is 30% growth in one year. And they expect nearly 21 billion things by the year 2020, which is growth by more than three times. This consulting firm announced a prediction that, by the end of 2020, some elements of IoT will be applied in more than 50% of major new business processes and systems.

### **3.2. Integrate digital factory and Smart Factory**

In order to make shorter and to improve planning (both product and production), the idea of the Digital Factory came up. When someone mention the Digital Factory term, it means that he implies general digital support of planning following the process chain from product development over process and product planning to production by using virtual working techniques. Based on this definition, it can be made a conclusion that the whole process of developing a product that is new has to be completely simulated prior to realization (this includes also a production equipment that is associated with that product). To sum up, term digital factory encompasses simulation of all activities (research, development and also production) which are conducting physically in the factory (Arndt, 2004, p.27).

The Digital factory is more than pure usage of simulation tools. It has impact on the organization of the factory and all activities in the factory have to be standardized (i.e. impact is on the whole workflow). At every step, data outcome of the workflow should be specified and then saved in a central database (of the whole factory). If it is determined by the process of simulation that the production will meet a given requirements (quality and time schedule), then it can be started with development and production (Arndt, 2006, p.28).

The Digital factory is the model of a real factory, and in the smart factory, this digital factory developed during engineering should be integrated with the real time data and inferred statistics and information of the smart factory. So, an important issue here is integration. Data should be received to the IoT platform of smart factory from IT applications of digital factory, with providing feedback.

### 3.3. Standardization activities in area of Smart Factory

Many standards development organizations (SDOs) such as the Institute of Electrical and Electronics Engineers (IEEE), the International Electrotechnical Commission (IEC), the International organization for Standardization (ISO), and the International Telecommunication Union (ITU) are working towards developing the Smart Factory standards. Also, some consortiums are working together with SDOs to promote standard technologies for the Smart factories. This standardization process will achieve interoperability, enabling information exchanged and understanding between different components of the Smart Factory.

If we want success of any industrial solution, we must keep cost and deployment effort low and guarantee high availability and durability during their lifetime. All of that is successfully possible only when those solutions are based on vendor independent open standards (Zuehlke, 2010, pp. 130-131).

It can be found in a significant number of sources that some authors suggest that IoT (Muhonen et al., 2015) is the most important technology concerning Smart factories, and it can be said that standards play important role in developing IoT. They allow all players to access IoT equivalently and to use it. The IoT standardization can include plenty of different standards, such as architecture standards, application requirements standards, communication protocol standards, information processing standards, data standards, identifications standards, security standards and public safety standards, and it is the reason of standardization's complexity. It is very important to have common standards in building a successful IoT system. Diverse standards and technical solutions will significantly slow down the development of IoT. The most relevant organizations related to IoT and industrial Internet are: ETSI, ISO, IEC and ITU. Also, there are some number of unofficial alliances and forums that play very important role (GS1/EPC Global, AllSeen Alliance, HART Communication Foundation etc) (Muhonen et al., 2015).

However, reliability and safety of these technologies under industrial environment should be certified in order to persuade users to forget existing control cables by future wireless connections (Zuehlke, 2010, p. 131).

In addition to devices' hardware, software and communication standards, design standards are also needed (Zuehlke, 2010, pp. 130-131). They enable achieving a seamless planning, design and operation environment.

There is no general, worldwide standardized model of the Smart Factory, but it exists for example a reference model that was developed by German Association of Electrical and Electronic Manufacturers. It is named the "Reference Architecture Model for Industry 4.0" (RAMI 4.0), and is considered as a key standard for Industrie 4.0.

RAMI 4.0 is a three-dimensional layer model that contains the most important aspects of Industrie 4.0, and its axis are: Hierarchy levels, Process (value stream process) and Architecture (FMEAE, 2016). The "Hierarchy Levels" axis are hierarchy levels from IEC 62264 series of standards (this series of standards describes enterprise IT and control systems) and IEC 61512 standard (which address batch process control). The "Life Cycle & Value Stream" axis represent the life cycle of facilities and products, based on IEC 62890 for life-cycle management for systems and product used in industrial-process measurement, control and automation. Architecture Axis consists of 6 layers. Those layers are: Asset, Integration, Communication, Information, Functional and Business (Amman Zaheer, 2017).

## 4. DISCUSSION

Today, the world is changing so fast. The appearance of IoT and many other new technologies has influenced not only the development of mobile communications, but also the industry. And, standards are the fundamental component of the evolution to smart systems. Term "smart", here, have informal meaning, i.e. it is something that has or shows a quick-witted intelligence. There are many examples of smart systems where standards play key role. We can talk about Smart cities, Smart farming, Smart Grids or Smart factories. Regardless of which smart system is considered, the influence of many international and national standardization organizations can be seen, as well as of the number of unofficial alliances and forums. Determining the real impact and the scope of standardization in those smart systems it can raise the awareness about the role of standardization.

The International Electrotechnical Commission pay particular attention to the Factory of the future, and worldwide many local initiatives support that idea. One of them, Industrie 4.0, which is in the focus of this study, is launched by German industrial associations encompassing VDMA, Bitkom and Zvei. As the key elements of these factory are identified (Monostori et al., 2016, pp. 621-641) cyber-physical systems (they are considering to be one of the largest advances in technology) and IoT, which is in accordance with literature. In order to ensure communication and control of cyber-physical systems it is needed to make a

standards based on an international consensus taking into consideration existing standards (national and regional) for industrial automation.

Furthermore, Gartner, Inc. is assured that, by the end of 2020, some elements of IoT will be applied in more than 50% of significant new business processes and systems. If it is achieved even only part of this prediction, it can be understood that without integration standards, as soon as possible, there will be a big variety of different protocols and impossible mission to integrate those systems.

However, the reality has to be considered as well. In this case of the Smart factory concept, that is the digital factory as a model of the real factory. Existing machines and equipment cannot be simply thrown away, forgotten, or a new factory cannot easily be built. That would be a very expensive investment that would not pay off at all. Therefore, the digital factory should be integrated with the real time data and inferred statistics and information of the smart factory. Again, the role of integration standards can be spotted.

At this moment, many formal and informal standardization bodies are working toward developing standards related to smart systems, and more specifically Smart Factories. Their efforts are directed toward information exchange between different components of that factory. Standards play important role also for the development of components for a smart factory. Good example is IoT, where standardization efforts are also present.

Due to the emergence of a large number of different technologies, it was needed somehow to find a way towards their integration. For this purpose, reference architecture models and integration standards are developed. The three-dimensional layer model RAMI 4.0, developed by German Association of Electrical and Electronic Manufacturers, was introduced. Research showed that, in this model, the standards are a key integrative element.

As we can see from smart factory example, there is no necessity to use certain standards. Everything is voluntary. Behind this volunteerism are hidden different motives. Therefore, some need to use those standards exists. By accepting those standards, their users are creating some habits.

All standards are accepted on a voluntary basis, regardless of motivation behind it. After a certain period of time, these standards simply become a habit. In many cases, their acceptance by the authorities also helps in that direction. This study was conducted using methods of analysis and synthesis, in order to review the key aspects of smart standardization and its contribution to the industry. It was concluded that the smart standardization is ubiquitous and it can be seen from the way the Fourth Industrial Revolution pays special attention to it. We should be aware of that there is so much to do in the area of standardization.

## **5. CONCLUSION**

In this study it was shown that standardization is very important element of new technological revolution. During time, conscience about standards has evolved to the level of smart standardization. All standards are accepted on a voluntary basis, regardless of motivation behind it. After a certain period of time, these standards simply become a habit, and that is the state we have today. In many cases they are promoted from the authorities which helps in direction of making them a habit.

Term “smart” is very often in the world of standards. There are many of them related to Smart city, Smart farming, Smart grid or Smart factory. But, the Smart factory is one of the most demanding projects today, because it is capable to collect, distribute and access to manufacturing relevant information anytime and anywhere. It includes horizontal, vertical and engineering integration. Many standards development organizations and some consortiums are promoting standard technologies for Smart factory, but there is no worldwide standardized model of it. Effort were made regarding the IoT standardization, which is the most important technology concerning Smart factories so it is expected that they will allow all players to access IoT equivalently and to use it. This will probably result in making IoT the backbone of the Smart factory.

The results of this study underscored the importance of standardization which is a key component in evolution towards Industrie 4.0. Common standards enable participation of a wide range of stakeholders (for example, companies), regardless of size or location. They help development of systematic, repeatable and efficient systems.

The topic is relevant and this paper can be used by students of the Faculty of organizational sciences as well as by those to whom standardization belongs to the domain of job description. The area of this topic can also be extended in some further papers to other areas of social activity, not only in industry, which would give a real picture of the impact of standardization in the present.

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# MODEL FOR APPLICATION OF THE BUSINESS CONTINUITY MANAGEMENT SYSTEM IN HIGHER EDUCATION INSTITUTIONS

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**Abstract:** *Using of exploratory and descriptive research in work points to the importance and the need of managing the continuity of business in higher education institutions. The aim of the paper is to propose a model of the management system to the continuity of business. Usage of this model will ensure to higher education institutions continuity of provision of education services to all stakeholders. The model is of a general character and can be applied in any higher education institution. Especially, the model is convenient for implementation in the Western Balkan countries in the context of reforms and development of higher education.*

**Keywords:** *business continuity management system, business continuity plan, ISO 22301, higher education institution, model*

## 1. INTRODUCTION

In recent years, a significant challenge for higher education institutions (HEI) is providing continuity in the process of using education services to its users, especially for those in transition countries.

The Business Continuity Management System (BCMS) offers a good response, because it represents the management system. The usage of such system would facilitate identifying potential threats and hazards, recognizing external and internal factors which influence risk increasing, defining measures that would reduce the probability of their occurrence, responding in case of their occurrence and continuing with providing services besides preserving the image and reputation of the institution (according to SRPS ISO 22301: 2014; 14).

By analyzing the relevant and accessible literature, the paper highlights the importance and advantages of business continuity management in the HEI. The main aim of the paper is to propose a model for the implementation of the business continuity management system in the HEI that would be enable continuity in the provision of education services by the HEI. The development of the model is based on the PDCA (Plan-Do-Check-Act) cycle, the life cycle of business continuity management and good practice examples of the HEI which were to a certain extent engaged in the continuity of business. The proposed model would create an environment for raising awareness of the importance of continuity in providing education services, as well as for improving the quality of education services.

## 2. METHODOLOGY

The principal method of research is based on existing theoretical results and examples of good practice in the specified field. The methodology of the research is based on the collection and examination of available literature, its analysis and systematization, with the aim of demonstrating the importance of business continuity management in the higher education institution, as well as the justification and utility of developing new model for applying the management system to the continuity of the provision of education services.

With regard to the type of research, exploratory and descriptive research was used in this paper. During exploratory research, international standards, reference documents and guidelines governing this field have been used in order to perceive BCMS in higher education institutions. Also, the exploratory research includes experiences of universities in the world that approached the implementation of the BCMS to certain extent, as well as publications available through the search of scientific and professional journals and index databases. The following key words were used for searching publications in electronic journals: Business Continuity Management System (BCMS), Business Continuity Plan (BCP), model, higher education institutions and risk. The search included published works in the last 12 years. In the use of the relevant literature, BCMS and BCP publications in higher education institutions have been prioritized, as well as more recent publications describing the risks to the higher education institution.

Currently, a relatively small number of scientific and professional papers on the subject of using the management system in higher education institutions and in general the implementation of the business continuity management system in higher education in the country and the region are available in the literature. One of the additional motives for this research is a particularly small number of researches on the BCMS, the methodological approach and the results of its implementation. The main purpose of this research is an attempt to point to the possibilities and benefits of the using of BCMS in higher education institutions and to propose a general BCMS model applicable to all higher education institutions, especially for those countries that are still implementing reforms in the higher education system..

### **3. BUSINESS CONTINUITY MANAGEMENT SYSTEM IN HIGHER EDUCATION INSTITUTIONS**

#### **3.1. General**

The continuity of business represents the ability of HEI to continue providing education services at an acceptable, pre-defined level after the incidence which causes a disorder (adjusted according to SRPS ISO 22301: 2014; 14).

In accordance with the previous said, Business Continuity Management (BCM) in a higher education institution is a holistic management process that identifies potential threats and risks to the institution, as well as their impact on the implementation of the process of providing education services (teaching process), if they are achieved. This way of management provides the basis for reducing the possibility of occurrence of unwanted events, increasing the ability to effective respond to unwanted events, protecting the interests of its key stakeholders and allowing the recurrence of activities to pre-disorder conditions as soon as possible. This is the way of protecting the reputation of the institution and enabling the fulfillment of the activities that create values (according to SRPS ISO 22301: 2014, 14).

Academic continuity points to the commitment of the institution in providing opportunities for the students and teachers to remain in the process of providing education services despite external influences and disorders (SchWeber, 2011, 68).

An early approach to business continuity management was focused on interruptions in information systems of organizations (Elliott, Swartz, & Herbane, 2007, 3), and it can be said that BCM literally derived from the world of information technology (Guide, 2009, 6). However, in recent years, the approach to business continuity management has become much wider. The broader consideration of capabilities of business continuity management is mostly influenced by the adoption of the ISO 22301 standard which defines the requirements for this type of management.

Herbane (2010, 978) BCM links to crisis situations and points to the fact that since 1970 BCM has been evaluated from form of management in crisis situations, as response to technical and operational risks that jeopardize the recovery of organization from the dangers and termination of business. Crisis situations can be defined as organizational functions or processes whose weak implementation can cause damage to stakeholders and further destabilize the reputation of institution (Coombs, 2014, 3).

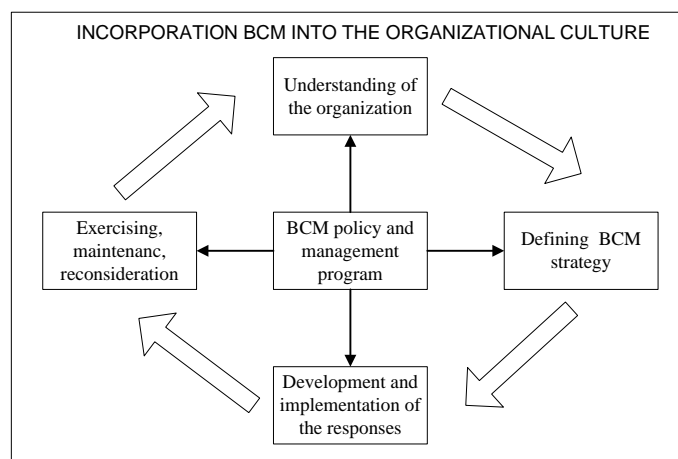
The general requirements, which refer to the business continuity management of an organization from the point of view of standards SRPS ISO 22301: 2014, include the following areas:

- understanding and determining external and internal factors that affect the ability of organization to achieve the desired results,
- understanding the needs and demands of stakeholders,
- leadership commitment to the BCMS in terms of defining the business continuity policy, defining roles, responsibilities and powers,
- the BCMS planning, in terms of considering risks and opportunities, as well as the measures applied to them,
- providing support, in terms of the necessary resources and their competence, accessibility, as well as the necessary and up-to-date information,
- planning and managing the processes that are necessary to meet the requirements and apply measures related to risks and opportunities,
- establishment, implementation and maintenance of process for analyzing business impact and risk assessment,
- defining a business continuity strategy, from which procedures and business continuity plans are obtained,
- evaluation of performance and improvements (SRPS ISO 22301: 2014, 26-54).



When it comes to terminology, methodology and requirements regarding this system, the authors Lindström, Samuelsson, Hägerfors (2010, 243-255) indicate that private sector employees are basically more aware of BCM concept and its importance than their colleagues in public sector. Anyway, whether it is a private or public sector, understanding of the business continuity management philosophy should be a strategic concern at the highest level within the organization.

For a higher education institution, it is important to promote business continuity management as one of the key values of the organizational culture, as shown in Figure 1 through the life cycle of business continuity management. This requires the commitment of the leader in the institution and communication with employees about this issue. Beside the leaders, employees need to understand how business continuity is linked to the purpose of the existence of the institution and how they can and should contribute to it in accordance with their roles, responsibilities and authorizations (according to with SRPS ISO 22301: 2014, 30).



**Figure 1:**The life cycle of business continuity management (in line with: GPG, 2010, 20; Cornish, 2007, 107)

Business continuity management and recovery after the incident aim to give BCM confidence that the quality of the service will be at the maximum level even during the crisis period and that the departments and institutions will be recovered as soon as possible (Guide, 2009, 2).

When it comes to higher education institutions in our area, the impression is that the theme of risk management in higher education is recently open issue, which is emphasized by the authors Ružić-Dimitrijević and Dakić (2014, 137-152).

Several authors points to the possibilities of applying this system in education but in the educational systems in the world (Asgary, 2016, 49-72; Durmo, 2016,57-74; McGuinness and Marchand, 2014, 291-310). Durmo (2016, 57-74) points to the importance and advantages of the business continuity plan and describes the BCM methodology. In his work Durmo points out that we should not proceed from the fact that the danger cannot happen to us and that the BCM should be seen as a huge competitive advantage. Asgary (2016, 49-72) emphasizes the importance of risk management and business continuity today, to the extent that York University has developed programs and courses in this field. McGuinness and Marchand (2014, 291-310) point to the practice of BCM in institutions in the United Kingdom. They also emphasize the importance of communication in case of incidents.

An analysis of the available university data in the world indicates that universities, although they do not have a certified system of business continuity management, to a certain extent, and in accordance with their needs and possibilities, deal with the business continuity, and most of all, by continuously planning their business. The key components of BCMS's for the higher education institution are the business continuity policy, personnel with defined responsibility, process management related to planning, testing and improvement of business continuity management, as well as internal documents which is a subject of audit and updating and which relate to the assessment risk and impact analysis on business.

### **3.2. Development of the model of business continuity management system in high education institutions in Serbia**

Bearing in mind that the universities in the world have realized the importance of maintaining their business (maintaining the continuity of providing education services) at any time and have worked on a well-defined framework of business continuity management, it is necessary that the higher education institutions accept

this concept and improve their business in this context, especially in the countries of the Western Balkans in the context of development and reform of higher education system.

If we take into consideration higher education institutions in Serbia, the greatest risk for the continuity of providing service by a higher education institution is the process of accreditation, namely re-accreditation. In the process of re-accreditation of higher education institutions, they have to fulfill the standards defined by the Rules on Standards and Process for Accreditation of Higher Education Institutions and Study Programs. Usually, in fulfillment of these requirements, the highest risk of the standard refers to teaching staff and space. First of all, it refers to teaching staff and their competence, in the sense of formal education, and in terms of representative references (published works), teachers' consent, i.e. the willingness of the parent institutions to give or even fulfill the conditions for retirement. Changes in the management structure of the institution also carry the risk if the leaders in the institution do not provide competent successors who are ready to continue with development of the culture of the previous management structure business. The challenge may also be space, in the sense that the institution does not have its own space, than renting it, where there is a change of purpose of space.

A significant threat that could jeopardize the continuity of a higher education institution is reduction of the number of students. This phenomenon can be the result of economic changes on the micro and macro plan (education financing, purchasing power of the population, price growth, state of the economy branches of interest, etc.). However, this phenomenon is not only a problem at the level of one higher education institution, it is a demographic problem at the state level.

An important step in the construction of such a system, especially for developing countries, is the raising of awareness among employees and its incorporation into the organizational culture and the value of the institution.

Building such a system in a higher education institution is a long-term process, which must be well-designed, with well-formulated strategy, designed business continuity plan and with respect to available resources.

In the development of a general model for the application of BCMS in higher education institutions (Figure 2), the basis was the PDCA cycle (Plan-Do-Check-Act) given in SRPS ISO 22301: 2014 standard.

The central place in the model is occupied by the basic processes of PDCA cycles which take place in a higher education institution in order to ensure the business continuity. Each of the elements of this cycle is further expanded by elements related to ensuring the continuity of the provision of education services.

In order for the institution to provide and respond to possible incidents, it is necessary to have a business continuity plan and a clear recovery strategy, which is ensured by business continuity planning. In the planning process, a higher education institution must take into account external and internal issues which are of importance for its ability to provide education services. It must also take into account the needs and expectations of stakeholders. The model also highlights the importance of the relationship between business continuity planning and stakeholders which realize an environment for continuous work in an institution, as well as support for students and other stakeholders in the learning process. It is very important that the top management demonstrates commitment in relation to the BCMS. When determining the BCMS, a higher education institution must necessarily examine the risks and define measures in order to reduce the adverse effects. The higher education institution should have competent human resources to carry out business in the context of ensuring business continuity with developed awareness of the importance of the BCMS (adjusted according to SRPS ISO 22301: 2014, 26-38).

According to Schweber (2011, 71), the key outcome of business continuity management is the plan of resistance, namely elasticity. Plans are not made for any possible situation that can cause interruption of work, already the effects of these interruptions are anticipated. For example, if there is a flood, a fire, a renovation, an expired lease of space, or a danger to chemicals in the laboratory, regardless of which of these events occurred in that institution, a certain period of time it can not continue to provide education services (Guide, 2009, 2). A business continuity plan must at least contain critical services and key activities and in which order they will be realized (i.e. defined priorities) if an emergency situation occurs (Resilience, 2014, 60). Every business continuity plan should be unique to the institution.

In accordance with the Best Practices in Business Continuity Planning in Higher Education (2010, 4-5) and SRPS ISO 22301 (2014, 40-48), the model also shows the BCMS implementation activities in a higher education institution, which refer to an element "Do":

1. *Business Impact Analysis* - This analysis identifies the critical processes of the institution, provides the maximum limits of estimation for delays and defines priorities among business processes for renewal.
2. *Risk assessment* – This assessment identifies specific threats for the institution, assesses the vulnerability of the institution for each threat and assigns a degree of risk to each potential threat.
3. *Risk management* - Analyzes the results of the risk assessment and defines the risks that require specific management, and the result of this phase is the documented widespread plan which defines the procedures necessary for restoring business processes to the original state in the event of an interruption.
4. *Testing, training and updating* - Determining the methodology which the institution uses in order to consistently train employees, test and update the plan and to communicate the plan between employees due to changes.

The plans need to be practiced and tested through an appropriate well-planned scenario in order to ensure that they are consistent with its goals. The reports on acquired experience arise as a result of exercises and testing, which are significant for recommendations and measures for implementation the improvement (SRPS ISO 22301: 2014, 46-48).

In the BCMS implementation process, it is important to determine a team that will be responsible for developing a plan and for managing the continuity of the provision of education services. The emphasis is on analyzing the impact on critical processes and activities, as well as on well-defined communication channels.

In the higher education institutions, critical business processes can be classified into one of three categories:

- Security and safety - all activities that are necessary to maintain a safe and a secure environment,
- Support processes - include activities which enable the financial sustainability of the institution and
- Learning, education and research - include activities and programs which support and realize an academic mission of the institution (Best Practices, 2010, 5).

Identification and protection of critical business processes and resources are needed for maintaining an acceptable level of business, protecting those resources and preparing procedures in order to ensure the survival of the institution at the time of interruption.

The elements related to checking "Check" and which are presented in the model, are: defining the criteria for performance evaluation of BCMS, internal checks, management review and management reporting. The higher education institution must know what monitoring and measurements implements and when implements them. As a result of training and testing of plans, monitoring and measurement and internal verification, changes in business continuity plans are being made, i.e. plans are adapted to new situations. Elements of the "Act" include: corrective measures, improvement and monitoring of system efficiency after improvement. After a certain period of BCMS application, some results of its application and outcomes can be seen, on the basis of which it is necessary to perform BCMS improvements. (according to PDCA and SRPS ISO 22301, 2014, 48-54)

In the development of the model, through the PDCA cycle, the basic activities are considered important for ensuring the continuity of the provision of education services by the higher education institution, as well as their interconnectedness. Evaluation processes can be recognized at the institution level (internal audits and performance appraisal of the BCMS) and at the national level (connection with bodies included in the monitoring and control system of the HEI).

Other significant components of the model are the requirements and expectations of stakeholders and their fulfillment that indicate the relation between the higher education institution and the environment. The environment, in which the higher education institution operates, includes direct beneficiaries (students) and stakeholders, as well as the relationships that the institution achieves with them. The stakeholders are the Government of a specific state, the competent Ministry, bodies involved in the system of monitoring and control of HEI, secondary schools and business entities. The relation that it realizes with stakeholders on the one hand can symbolize social responsibility in terms of ensuring the continuity provision of services of education, which defines the relationship of the institution according to the set requirements of the environment and the level of their fulfillment, but on the other hand, the autonomy of the institution that is reflected in defining of their own goals, policies, strategies and plans, and continuous monitoring of their own results in order to be achieved and constantly improved. The relations with interested parties show that in higher education there is general dependence on the economic, political and social structure. Although the higher education institution has its own autonomy, it is integrated with multiple connections into social and economic affairs with increasing influence that individual stakeholders realize at the institution (the

Government, the competent Ministry, business entities, students, etc.). It is emphasized that the model is dependent from the organizational culture.

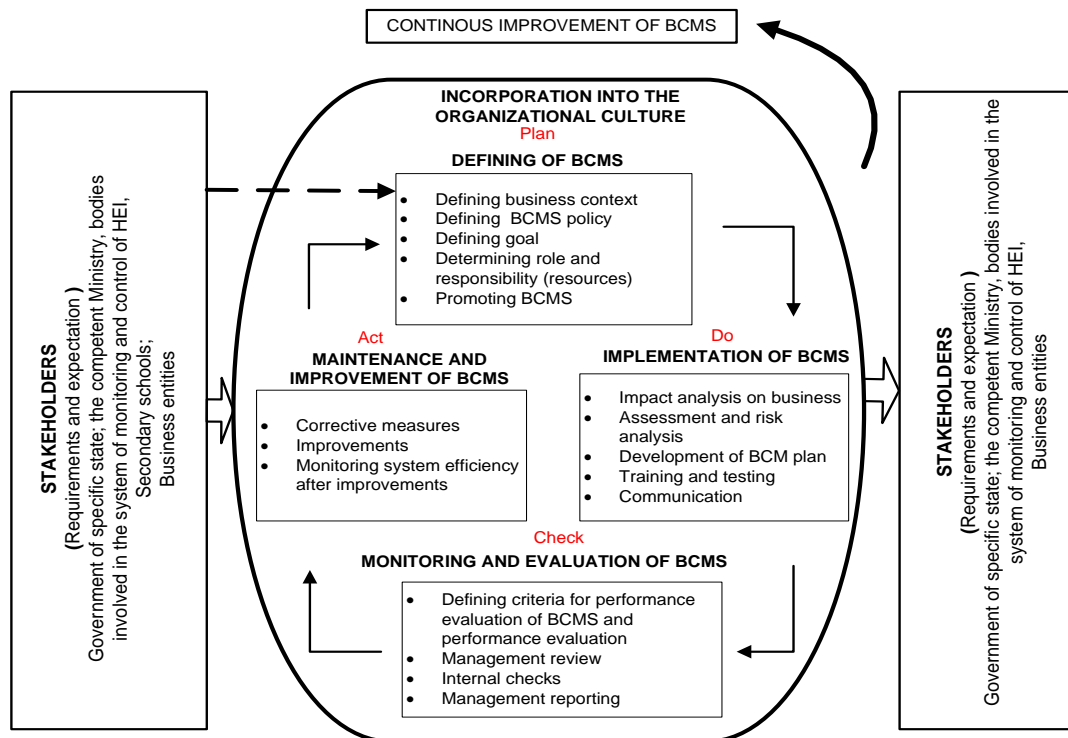


Figure 2: Proposal of BCMS model for higher education institutions in Serbia (harmonized with PDCA cycle and ISO 22301)

Based on the set model, it is possible to obtain a valid picture of the processes which take place in a higher education institution in terms of ensuring the continuity of the provision of education services. In this respect, the proposed model justifies its application by providing a good basis for ensuring the continuity of the education process. The model can be applied in order to:

- facilitating higher education institutions to improve the quality of education services,
- increasing the ability of the institution to absorb, react and recover from disorders,
- ensuring the continuity of the provision of education services,
- encouraging the implementation of BCMS in higher education institutions,
- facilitating the management of the institution by giving recommendations in the planning process, but also by other processes,
- creating an institution's resistance to disorders from the internal and external environment, and inter alia for achieving a competitive advantage over other higher education institutions.

The significance of this model is reflected in its ability to serve as the basis for the development and application of the business continuity management system.

Considering above, it can be seen that the business continuity management is not a set of some specific processes that need to be kept in reserve for some extraordinary circumstances, which can certainly occur at some point. The elasticity of operations at the operational and cultural level may be the best solution in the preparation of the institution for extraordinary activities, with providing additional resources and flexibility that permeates all academic and business activities of the higher education institution (Yanosky, 2007, 157).

BCM presents one type of investment whose benefit and return can hardly be determined as in other strategic investment decisions (Kato and Charoenrat, 2018, 578). The ultimate goal of the BCM is to build the resistance of the institution and ensure the provision of services, despite damage to property and the lack of necessary resources caused by an unwanted event (Guide for SMEs, 2011).

#### 4. CONCLUSION

Research and analysis of relevant literature, which refer to ensuring continuity of business in higher education institutions, have resulted in the development of a model for the implementation of the business continuity management system in conditions of interaction with stakeholders in the environment. The model

has been developed on the basis of the PDCA cycle and systematically provides the basis for understanding the basic activities in terms of ensuring the continuity of the provision of education services.

The PDCA cycle, extended by elements related to ensuring continuity in the process of providing the same service, is a good basis for ensuring the quality of education services and the right solution in the context of reforms and development of higher education system, especially for Serbia and other countries of the Western Balkans.

The proposed model is of a general nature and should help higher education institutions in undertaking a comprehensive approach to ensuring business continuity, enabling them to connect with already established processes, which was the goal in developing the model.

The development of the model has arisen from the need to systematize in a comprehensive manner and show the activities of planning, providing, managing and improving the continuity of the provision of education services. The model defines the business continuity management system in conditions of external relations with stakeholders, from the perspective of a higher education institution. The proposed model gives freedom to higher education institutions in defining their own activities in terms of ensuring continuity of provision of education services, but basically keeps the PDCA cycle as the core of the management of the institution. In realistic implementation of this model, leaders in the institution play an important role in the context of their commitment and the development of awareness among other employees of the significance of such a system.

In theory, this work has resulted in a deeper consideration of the meaning and importance of planning business continuity in higher education institutions and, in general, the importance of application of BCMS in higher education. Considering the insufficient research of this phenomenon, the basic contribution is also reflected in the definition of the general model proposal for the implementation of BCMS in a higher education institution. The developed model can be applied to all types of higher education institutions. Considering the insufficient research of the BCMS problem in higher education institutions, this model can serve as a basis for further research in this field, as well as for reviewing the introduction of certain changes in higher education institutions in our area. In this respect, a new challenge has been posed to the higher education system in Serbia and in other countries undergoing reforms of the higher education system.

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# INFLUENCE OF SOME ASPECTS OF DISTANCE LEARNING ON QUALITY OF STUDYING

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**Abstract:** *The great influence that online learning has on the quality of studying is the importance of observing and analyzing the correlation between the acceptance of online learning among students and their success at college. From the student's point of view, the success of the faculty is considered to be the result of their learning, and in this paper it is expressed through an average grade. The aim of the research is to determine the influence of online learning on the quality of studying. For comparison of these two factors, the questionnaire and the ANOVA test were used, as well as the selection, analysis and synthesis of the collected information in order to obtain the most relevant data. That's exactly the main contribution of this research. Given that there is a small number of papers that explore this issue, this research has a vital importance for the area to which it relates. The analysis carried out concluded that there is an influence of online learning on the quality of studying, but that a large number of students are not yet ready to replace traditional learning with distance learning.*

**Keywords:** *distance learning, online learning, quality of studying, e-learning, e-learning tools*

## 1. INTRODUCTION

The traditional context of learning is experiencing a radical change. Teaching and learning are no longer restricted to traditional classrooms. Electronic learning referring to the use of electronic devices for learning, including the delivery of content via electronic media such as Internet, audio or video, satellite broadcast, interactive TV, CD-ROM, and so on has become one of the most significant developments in the information systems industry. With the evolution of wireless networks, it is easy to understand how the mobile devices have gained importance in day-to-day life and in education, too. Today many students want to learn online and in turn get degrees from worldwide colleges and universities, but still cannot go anywhere as they live in isolated areas without proper communication systems. Consequently, many researches encourage learning courses under the e learning system as it saves time and energy of those students staying at any far off distant regions from the universities or colleges they have enrolled. There is also a financial impact. Networks and access to online materials offer an alternative to place-based education which reduces the requirement for expensive buildings, and the costs of delivery of distance learning materials. Although studies and statistics show that between 20 and 30% of those students who begin a distance-learning course do not finish it in the last few years there has been sharp growth in the size of the distance learning market. One of the most important factors relating to e-learning is the element of interaction. Distance students, due to their backgrounds, may also feel more pressure to collaborate and be part of the team (Valentine, 2002).

The need for education has changed because of an increased demand for a highly educated workforce who will be expected to learn continuously. E-learning has become an increasingly important part of higher education. However, the employment of distance education by universities and colleges highlighted issues relevant to the quality and effectiveness of online distance higher education compared to conventional educational patterns. Faculty positive attitude to ICT also does affect the students' perceptions of their distance learning experiences (Valentine, 2002). A lot of evidence has been also provided that the quality and quantity of communication give a raise to the overall student learning perception and satisfaction (Sloan, 2002).

## 2. LITERATURE REVIEW

The rising use of internet and supporting systems constructed the innovative and easy learning environment for students to acquire more skills and knowledge. ICT has transformed the conventional based education system into technology based education system. The classroom environment is moved from teacher centered to student centered form. The radical changes in educational technologies prepared the students to be more responsible in their learning. Viciano et al. describe a computerized system that allows researchers creating, applying and tabulating surveys and paper instruments in an automatized way and consider them

as a useful tool since it permits to input data with higher precision and no need for previous codifications. According to Granados (2015), the use of ICT means breaking with traditional media, boards, pens, etc., and it has given way to a teaching role based on the need for training in and updating one's knowledge of teaching methods based on current requirements.

Recent studies have shown that e-learning implementation is not simply a technological solution, but also a process of many different factors such as social factors (Schepers and Wetzels, 2007; Tarhini et al., 2014b; 2015), and individual factors (Liaw and Huang, 2011), organizational such as facilitating conditions (Sun and Zhang, 2006) in addition to behavioural and cultural factors (Masoumi, 2010). Such major factors play an important role in how an information technology is developed and used (Kim and Moore, 2005). Recent studies have shown that a basic element in traditional classroom learning is communication among the students: the ability to ask questions, to share ideas with others, or to disagree with others is a basic need in the learning process (Picciano, 2002).

Martino (Martino, J., (2007) & Van den Brekel (Van den Brekel, A.J.P., (2007)) found that Virtual environments are best substitutes for those students unable to attend traditional face to face teaching systems. According to A., Jamaluddin, Virtual experiments give great environment for Teaching & Learning (A., Jamaludin et al., (2009)). Fatih Baris and Tosun described the influence of using e-tools in the education process at the high school and concluded the positive influence of this tool on students. More than anything else (34.8% in our research), flexibility is what makes e-learning programs attractive to the learners (Schoech, 2000). In distance-learning courses students can take courses from preferred locations that are convenient for their schedules. This advantage is appealing to most adult learners because it accommodates their work schedules and permits flexibility to manage their family life (Kember, Lai, & Murphy, 1994). Distance students, due to their backgrounds, may also feel more pressure to collaborate and be part of the team (Valentine, 2002).

For beginners, it has been reported that confronting computer technology was more stressful and consumed more time than the actual learning activities at the beginning of a course (Atack, 2003; Atack and Rankin, 2002; Billings et al., 2001; Scollin, 2001). In addition, feeling isolated and missing social contact have been reported in studies of computer-assisted learning. Particularly, the absence of non-verbal cues in solely Web-based learning left students feeling they have been communicating largely with a machine rather than other human beings (Atack and Rankin, 2002; Billings et al., 2001; Andrusyszyn et al., 1999; Bullen, 1998).

The fact that gaps in one's knowledge may be compensated for, and are complemented by virtue of, the knowledge of such person's classmates, constitutes an important advantage of learning in a group (Picciano, 2002). Moreover, people who work together provide social and emotional support to each other (Haythornthwaite, 2001). Different research studies (Lai, 1997; Klemm & Snell, 1996; Jonassen & Kwon, 2001) assert also that subjects that involve discussion, brainstorming, and reflection are best suited to the online format despite the fact that online discussions are significantly different from face-to-face discussions. Courses must be designed so that students could benefit from the interactive potential of online learning (Thorpe, 2002), so instructors require extensive training on how to utilize new technologies and adapt teaching methods to distance learning environment (Valentine, 2002).

Faculty positive attitude to ICT also does affect the students' perceptions of their distance learning experiences (Valentine, 2002). A lot of evidence has been also provided that the quality and quantity of communication give a raise to the overall student learning perception and satisfaction (Sloan, 2002). Gibbs and Simpson (2004) advocate for regular, comprehensive, and detailed feedback as the main interactive component of teaching. They conclude that only immediate and specific feedback provided by instructors enables students to gain control over their learning and monitor their own performance.

Individual background variables found to have an impact on students' acceptance of e-learning are: gender, learning styles, age and organizational factors (i.e. school). Gender seems to be the most influential background factor as it affects the level of computer anxiety (Shuell & Farber 2001), perceived usefulness and ease of use (Shuell & Farber 2001, Ong & Lai 2006). A direct relationship between gender and acceptance is also proposed by Mitra et al. (2000), who concluded that men were more positively predisposed toward computers and tended to use computers more than women. Age influenced students' levels of computer confidence, as younger students were not so anxious in using computers (Jennings & Onwuegbuzie 2001).

The quality of higher education is affected by many requirements and some of them are requirements by (Lazic, 2007):

- Beneficiaries of higher education - stakeholders
- Bologna process, international standards and international organizations (international requirements)



- Requirements of national standards for accreditation,
- Quality management system requirements,
- Requirements of the standard of work and higher education institutions and
- Requirements of technological standards of work or pedagogical subsystem.

### 3. RESEARCH METHODOLOGY

#### 3.1. Aim of this research

The aim of this research is to see what way of studying is the best for Serbian's students, what students prefer in their learning and what are the biggest problem in distance learning. As well the aim of this study is to examine are the students ready to replace traditional way of learning by distance learning and to see what aspects of quality studying have influence on distance learning.

#### 3.2. Research questions and hypothesis

The first distance learning system was developed in America in the 1960s and has a huge impact on learning in developed countries today. On the other hand, the fact that Serbia is still a developing country, this system began to develop several years earlier. In the beginning, he encountered the great resistance of the supporters of the traditional way of learning, while today, every year, the number of students who are interested in this form of learning grows. Two research questions and three hypotheses can be defined about influence of quality of studying on distance learning in Serbia in this paper:

- **Research Question 1** - Most students in Serbia considered that online learning make studying easier.
- **Research Question 2** - The largest number of students is not yet ready to replace traditional learning with online learning.
- **Hypothesis 1** - The basic criteria of the student's success (average grade) have no impact on using online learning among students.
- **Hypothesis 2** - Availability of materials has the greatest influence on the quality of studying.
- **Hypothesis 3** - The biggest obstacle (barrier) to online learning is the lack of social interaction.

#### 3.3. Population and sample characteristics

The population of this research are students from Serbian universities. In this paper were used online questionnaire as method for collecting data that will be used in this research. The questionnaire was sent to 150 random Serbian students and only a few of them were not usable. The respondents were male and female students from first year to graduate year of study. Most of them (42%) were 2<sup>nd</sup> year of study. They cover almost every field of study. Majority of respondents are from technical and engineering fields of study. Priorities was faculties that have developed system of online learning. As well the most respondents were students who spend more than 6 hours on the Internet (58%).

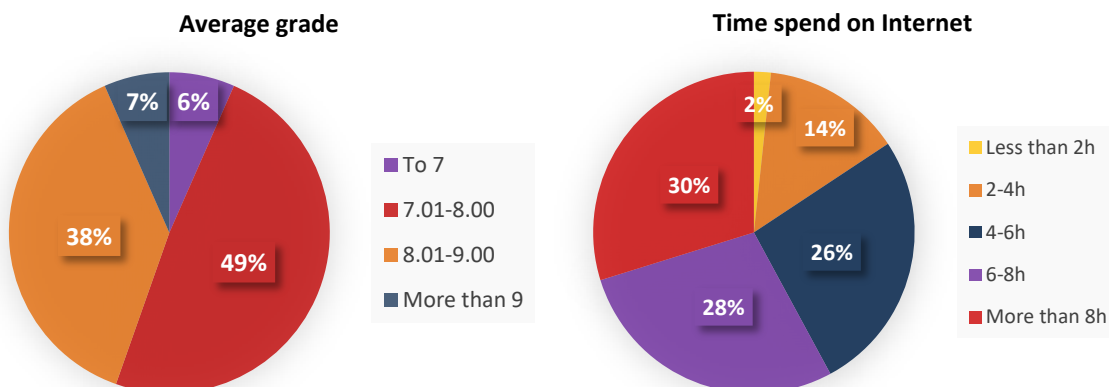


Figure 1: Basic information about average grade and time spend on Internet

#### 3.4. Research instrument

Questionnaire was created and distributed online. It was consisted of three parts. First one was related to basic criteria of the students success about respondents. Those included: time spend on Internet, year of

study and average grade. Second part included questions about students way of learning and different e-tools like are online courses, online tests, online dictionaries and searching literature. Questions in third part were about influence of different aspects of quality on distance learning. This include influence of appearance of the interface, availability of materials, interaction with the professor and flexibility in learning on online learning. They consisted from Likert scale, where one is extremely small influence and five is extremely big influence.

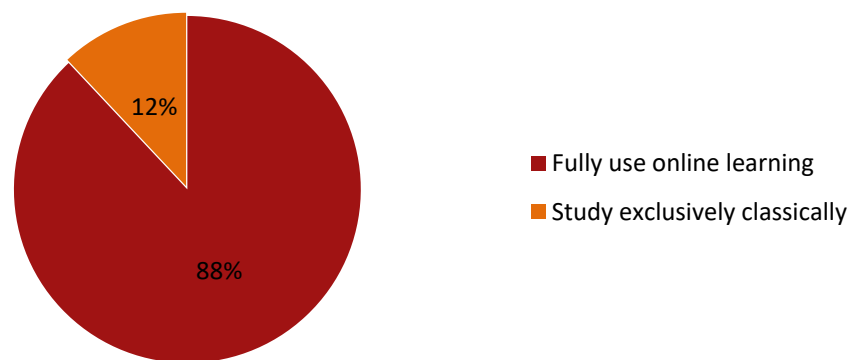
#### Data Analysis Methods

To examine above mentioned hypothesis, after conducted questionnaire, statistical analysis was performed using SPSS 22. Various tests were used in order to get most precise data.

### 4. RESULTS

To support the following results, sample characteristics were collected and analyzed. Some of them are more particularly described by giving the answers to some basic questions related to distance learning. One of them is “Do you use any types of electronically supported learning (online learning) during your studies?” The results are represents on picture 2.

**Do you use any types of electronically supported learning (online learning) during your studies?**

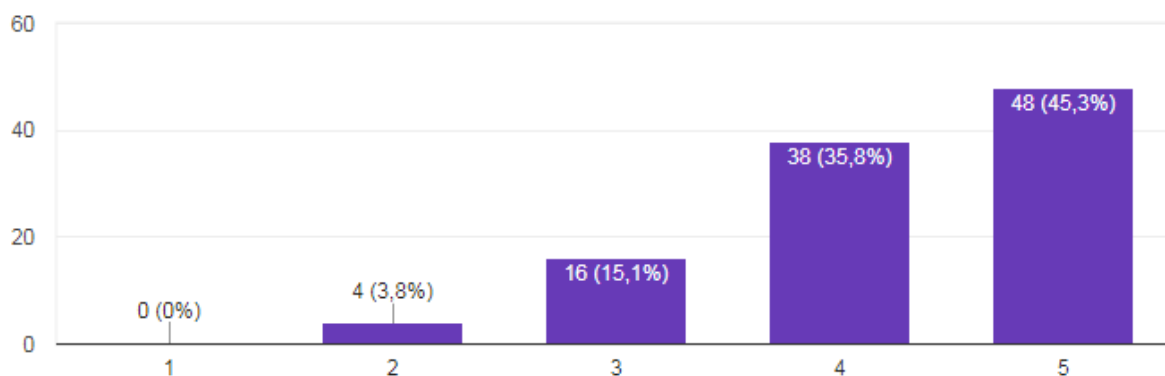


**Figure 2:** Uses of online learning among students

Now, will be represented the results of two research questions and three hypotheses.

#### **Research question1 - Most students in Serbia considered that online learning make studying easier.**

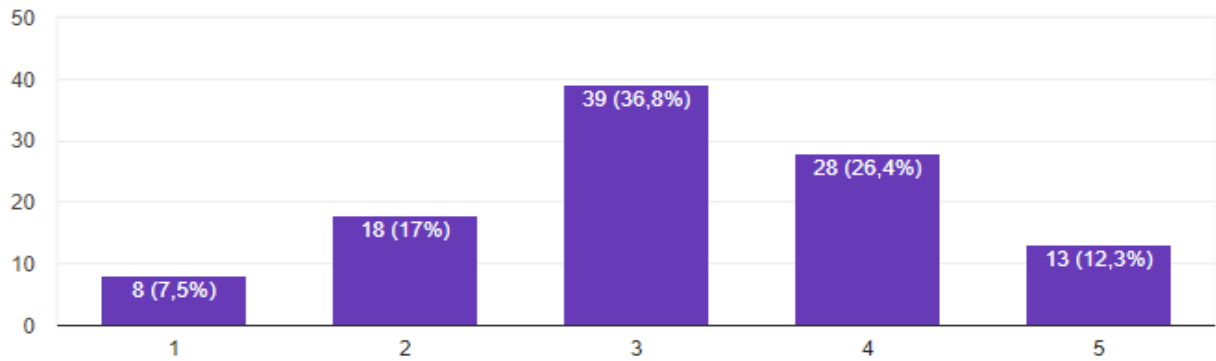
Turned out that thatwas right. Using questionnaire it can be proved that most students in Serbia considered that online learning make studying easier. Question consisted from Likert scale, where one is extremely small influence and five is extremely big influence. The results of this research are given on the figure 3.



**Figure 3:** Positive impact of online learning on studying

**Research question2 - The largest number of students is not yet ready to replace traditional learning with online learning.**

Using questionnaire, results show that students are not yet fully prepared to switch from traditional way of learning to online learning. Question consisted from Likert scale, where one is extremely small influence and five is extremely big influence. The results of this research are given on the figure 4.



**Figure 4:** Student willingness to replace the traditional way of learning

**Hypothesis 1 -The basic criteria of the student's success (average grade) have impact on using online learning among students.**

Using ANOVA test it can be concluded that this hypothesis turned out to be right. Significant influence does exist and it is less than 0.05. Average grade truly have impact on using online learning among students. The results of this research are given in the table 1.

**Table 1:** Average grade and online learning

Influence of average grade on using online learning	Descriptives		
	N	Mean	Std. Deviation
To 7.00	9	2,44	,726
7.00-8.00	59	1,66	,685
8.00-9.00	45	1,69	,596
More than 9	8	1,50	,535
Total	121	1,72	,674

### **Hypothesis 2 - Availability of materials has the greatest influence on the quality of studying.**

Using ANOVA test, significant difference was not recognized, considering availability of materials as an aspect of online learning and quality of studying. P value was greater than 0.05. The results of this research are given in the table 2.

**Table 2:** Literature and quality of studying

Influence of literature on the quality of studying	Descriptives		
	N	Mean	Std. Deviation
Mostly does not influence	7	4,71	1,604
Partly influence	17	4,76	1,786
Mostly influence	8	4,12	2,100
Completely influence	25	4,96	1,620
Total	57	4,75	1,714

### **Hypothesis 3 - The biggest obstacle (barrier) to online learning is the lack of social interaction.**

Using ANOVA test it can be concluded that hypothesis was right. Significant influence does exist and it is less than 0.05. The results of this research are given in the table 3.

**Table 3:** Social interaction and online learning

Influence of social interaction on online learning	Descriptives		
	N	Mean	Std. Deviation
Mostly does not influence	10	1,40	,516
Partly influence	32	1,38	,492
Mostly influence	35	1,57	,502
Completely influence	29	1,72	,455
Total	106	1,54	,501

## **5. DISCUSSION AND CONCLUSION**

Information systems are something that is constantly evolving. With the development of information systems, learning methods are being developed. Thus, it is possible to hear terms such as distance learning, online learning, and so on. Due to the enormous importance of the influence of online learning on the quality of studying, we decided to look more closely at this topic. The aim of this research is to examine whether students are ready to replace traditional way of learning by distance learning and to see which aspects of quality study have a bearing on learning distance. Also the aim of this study is to see which way of studying is best for Serbian students, what students prefer in their learning and what is the biggest problem in distance learning. Based on the research, we found that most students in Serbia considered that online learning makes learning easier and most students use some aspect of online learning, but the largest number of students is still not ready to replace traditional learning with online learning and the reasons for this are mainly lack of social interaction, lack of interaction with professors, etc. It can be concluded that online learning in Serbia is still in the development phase and it is necessary for students to learn more about the benefits of online learning.

Results from first research question proved that most of Serbian students considered that online learning make studying easier. This refers to thought on some e-tools like online courses, online dictionaries,

searching literature and online tests. Fatih Baris and Tosun described the influence of using e-tools in the education process at the high school and concluded the positive influence of this tool on students.

In second research question, it can be concluded that the largest number of students is not yet ready to replace traditional learning with online learning. Only one third of students who participate in survey said that are ready to replace traditional learning with distance learning. This show that student must be more informed about advantages of distance learning.

In first hypothesis, it can be concluded that there is significant difference between average grade that student have and using online learning. That means that students who have higher grades, using online learning more than students who have lower grades. That shows that student who have higher grades are more opened to try something new in learning. This is telling that students with lower grades accept things that are easy to use and that require minimum effort and they have no interesting in trying some new ways of learning, like online learning. But some students aren't conscious that online learning can make study a lot of easier.

Results from the second hypothesis were interesting. Some thoughts are that availability of materials has the greatest influence on the quality of studying. But this is not right. It seems that there is no significant difference between availability of materials and quality of studying. That means that availability of materials have the similar influence on quality of studying like others aspect of online learning.

By the third hypothesis is proved that the biggest obstacle to online learning is the lack of social interaction. Picciano (2012) concluded that a basic element in traditional classroom learning is communication among the students: the ability to ask questions, to share ideas with others, or to disagree with others is a basic need in the learning process. Also, Atack and Rankin, Billings, Andrusyszyn and Buleen says that feeling isolated and missing social contact have been reported in studies of computer-assisted learning. Particularly, the absence of non-verbal cues in solely Web-based learning left students feeling they have been communicating largely with a machine rather than other human beings. Research has proven that, indeed, social interaction is something that students most miss in online learning.

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## OVERVIEW AND FUTURE OF QUALITY MANAGEMENT CONCEPTS IN ADDITIONAL AIRLINE SERVICES IMPROVEMENT

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**Abstract:** *In this paper, we discussed the importance of additional services in airlines, their quality and related quality management approaches. Different concepts of providing additional services for both organizations that offer full service and low-cost organizations are presented. We overviewed wide range of services in airline industry, and dedicated special attention to the additional services. The paper also deals with problems related to the definition of quality and quality assessments of these services, followed by the example of RATER model and its use. Key elements of the Gap model are analyzed in order to provide understanding of customers' expectations and perceptions, along with business performances in context of basic quality planning, control, improvement and assurance activities. At the end, new challenges for improvements of additional services in airlines, as well as potential overall advancement of the system perspectives are presented. We concluded that additional airline services will continue to grow along with the trend of adjustment to different groups of customers, thus creating even wider possibilities for the customers. As the new technologies will enable growing information, one of the best mechanisms for achieving greater customer satisfaction and successful business is the use of quality management concepts in this field.*

**Keywords:** *quality management, airlines, additional services, chargeable services, non-chargeable services, improvement*

### 1. INTRODUCTION

Although we are learning from ancient myths about the attempts of flying from men Dedail and Icarus and the traces of ancient Chinese civilization, the history of aviation can be accommodated in the last 100 years. From the time when the Wright brothers in December 1903 performed the first flight with a heavily air-borne, managable drive, the aviation's rapid development began. The first regular airline company was DELAG (Deutsche Luftschiffahrts-Aktiengesellschaft) and it was founded in 1909 with the help of the German government and Cepelin Corporation (Schmitt and Gollnick, 2016). During the First World War, bomber planes were used, and the largest could carry a load of up to 5 tons. In 1919, the first flight was made across the Atlantic, and between 1920 and 1930 there was also progress in the field of civil aviation. The first commercial passenger plane was Douglas DC-3. From this period there are companies that exist today - RDA (Royal Dutch Airlines) founded in 1919 and Qantas (Queensland and Northern Territory Aerial Services) from 1920.

After the Second World War there was a further development of civil aviation thanks to the overflow of resources from the military sector. In 1956, American Airlines transported more passengers than US railways, and in 1957 more passengers crossed the North Atlantic by plane than by boat. Significant events in the development of aviation took place in 1958, by introducing Boeing 707 as the most economical, then Airbus in 1970, and the first plane on solar and electric power in 2010. The largest and most comfortable airplane today is the Airbus 380 with a capacity of 850 up to 1000 passengers.

Over the years, most airline companies were established at the national level and operated in accordance with state interests. However, globalization and new ownership relations and the strengthening of competition lead to permanent changes in the market. The airline's independent operations are more difficult now, so that they associate themselves in partner groups to unite their strengths and resources. Consequently, competitors become strategic business partners, and their cooperation takes place in commercial and operational businesses such as: flight scheduling, marketing, frequent flyer program, and codeshare (bound flights).

Examples in this paper are inspired by the practices of some of the most famous alliances:

- Star Alliance – Lufthansa, SAS, Thai International, United Airlines;
- Oneworld - British Airways, American Airlines and Cathay Pacific;
- Skyteam – Air France, Delta Airlines, KLM, Aeromexico, Aeroflot and Korean Air (Szakal, 2017);

## **2. AIRLINES AND THEIR SERVICES**

Airlines are inherently unique and operate in a unique and different way in comparison with other companies. The basic function and purpose of the existence of airlines is to provide the service of safe and efficient passenger transport from point A to point B. Regarding the basic service, different airlines may include a variety of accompanying and additional services. Additional services complement the quality of the basic service and increase its value. In low cost companies (LCC), the price of the ticket includes only basic passenger transport services, while all other services are considered as additional and charge separately. Full service companies (FSC), in addition to the basic transportation services, include tickets, luggage transportation to a certain weight, flight overnight and other services depending on the selected class. Most of them offer two basic categories - service classes: economic and business.

The economic class includes seats in the central part of the aircraft, luggage within the permitted dimensions, meals and entertainment depending on the length of the flight. Business class passengers can use Premium lounge services, and within the airplane they are sitting in comfortable seats that can stretch and order meal and drinks as desired at any time, and have more options for fun.

On the other hand, many companies offer services to their customers grouped into packages with a distinctive tariff name. For example, the company British Midland International (BMI) classifies several types of packages (economy saver, economy, economy flexible and business) and depending on what service they choose (checking and scheduling, acquiring rights for loyal passengers or some additional benefits) customers gain the right of advantage in checking, collecting and doubling miles or the ability to read newspapers or the use of hot and cold meals and alcoholic drinks (Vinod and Moore, 2008). All other services outside the basic package are considered as additional, so they can be chargeable and non-chargeable, and it is needed to make a special requirement when booking a ticket.

### **2.1. Chargeable services**

Additional services (ancillaries) that are charged separately are optional services that a customer can buy along with the ticket. The airline decides which service will be chargeable and under what conditions. For example, a particular service may be chargeable for one destination, and for the other not, the service may be chargeable to an economy class, and free for business, while frequent flyers may be exempted from paying additional services. Some additional services can be purchased exclusively with the airline tickets, while other services can be purchased as a separate service, with or without booking a flight. The spectrum of chargeable services can be very wide and varies from LCC to FSC. The payment services can be classified into three groups (Marcenko, 2015):

- 'A la carte';
- Commission – based ancillaries (third party services);
- Frequent flyer programme – (services intended for frequent flyers).

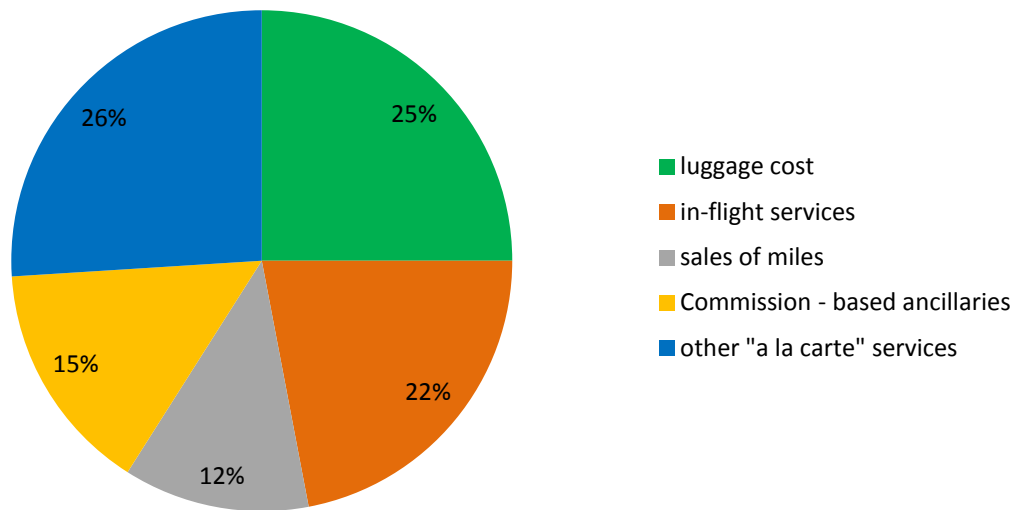
The passengers have the opportunity to use such a varieties: food and beverages during the flight, an advantage in "check-in" and boarding, luggage, seats with extra legroom, fun during the flight, wi – fi, etc. are included in 'a la carte' services. Provision-based services relate to hotel accommodation, car rental and travel insurance, while services intended for frequent flyers allow discounts on airline or other product prices (wrist watches and hotels). Together with basic (transport), additional services round up the entire package offered by one company to the passenger (O'Connell and Warnock, 2013).

#### **2.1.1. The economic significance of chargeable services**

Airlines make significant revenues from additional services (Figure 1). Key services with the largest share in the revenue from chargeable services are luggage transportation (25%), a la carte services during the flight

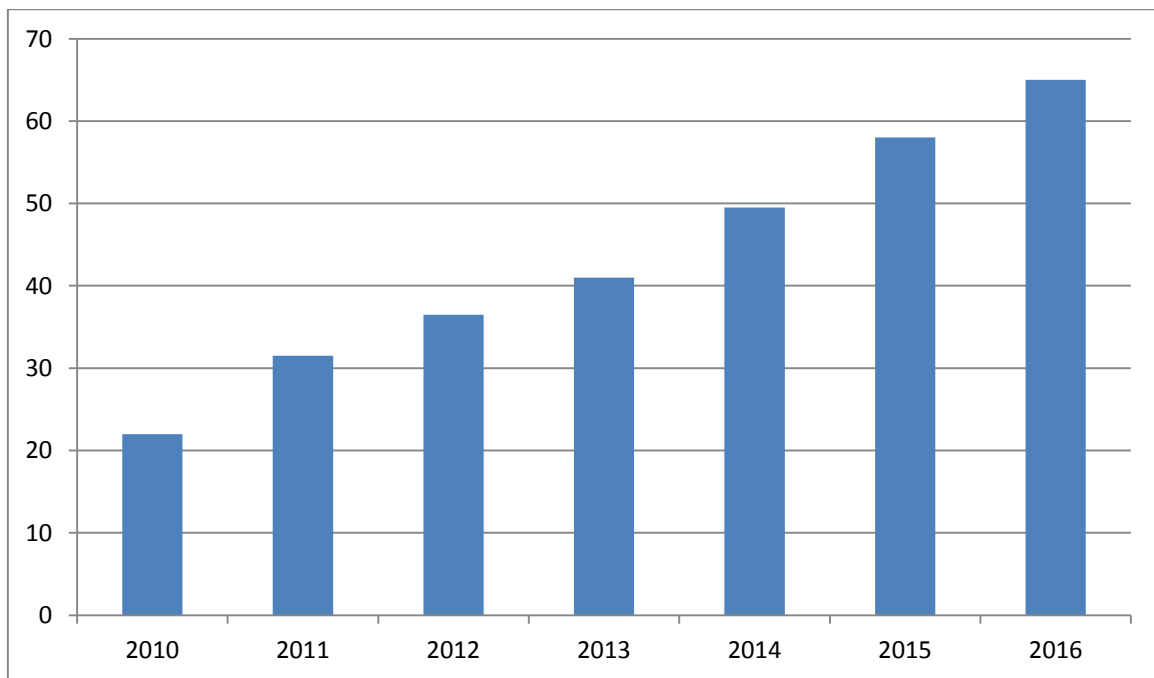


(26%), commission based services (15%) and sales of miles for frequent flyers (12%) .



**Figure 1:** Key components of the revenue from additional services (Idea Works Company, 2016)

Revenue from additional services as well as its share in the overall revenue of airlines, grows year after year. Figure 2 shows an increase in the revenue from additional services ranges from \$22 billion in 2010 to \$65 billion in 2016. At the same time, the increase in revenue is recorded from additional services against the total revenue of 9.2% in relation to 4.6% in 2010 (Amadeus IT group, 2017).



**Figure 2:** Total revenue from additional services (\$ billion)

## 2.2. Non-chargable services

Companies that provide a complete service, within the price of the ticket, allow passengers and a range of other services that make travel easier, and to get those services, they need to submit a special request. Some of them are: the use of a baby basket, a meal for children or special meals, the use of wheelchairs, transport of bicycles, musical instruments, sports equipment, passengers with reduced mobility, persons with special needs, those who require special medical care, medical carriers, dogs to help blind, deaf and psychiatric patients, the transport of fragile luggage and weapons, etc. Each passenger has the right to use

these services, but it is necessary to make a special request when booking a ticket. The company is obliged, in accordance with its procedures, to consider and assure the execution of the request.

### **3. QUALITY MANAGEMENT OF ADDITIONAL SERVICES**

Quality management is a set of coordinated activities to direct and control an organization in terms of quality (ISO, 2015). All quality management activities are grouped into four processes: planning, control, improvement and quality assurance.

Quality planning is determining the quality objectives by examining the needs and requirements of the customers, translating them into the service specification and planning the necessary resources for the service realization. This phase of quality management includes the design of all processes by providing answers to the questions: who are customers; what are their expectations; how to meet expectations; what resources are needed?

Quality control focuses on meeting the quality requirements and includes the activities of monitoring, controlling and reviewing all activities involved in the service delivery process. It aims to realize planned, i.e., projected quality, permanently, with as few variations as possible. It answers the following questions: whether we are able to fulfill the expectations of the customer; to what extent we fulfill the expectations of the customers; whether we constantly meet the expectations of the customers; whether we are implementing preventive and corrective measures. Quality improvement should enable increased ability to meet quality requirements and involves the implementation of preventive measures for setting up and implementing a new higher quality. Answers to questions: how to improve the quality of service; how to overcome customers' expectations.

Finally, quality assurance aims at assuring that the quality requirements are met. It represents a system of policies, procedures and practices that result in a consistent service in accordance with predefined quality requirements. It is necessary to answer the question: Do we apply policies, practices and procedures?

One of the ways to assure quality is the implementation of international standards. The specific standards, guidances and guidelines developed by the IATA - International Air Transport Association apply to the airline industry. This international airline association was founded more than 70 years ago in order to help companies to cope with their processes and increase customer satisfaction with cost savings and efficiency gains (IATA, 2017). IATA develops standards, instructions and guidelines that enable airlines to safely, efficiently and economically operate according to strictly defined rules. At present, 275 airlines have IATA accreditation. With integrated quality management system and security management system, IATA provides evidence of efficient and effective business in the field of quality and safety for all interested parties.

#### **3.1. Defining the quality of additional services**

Quality is the degree to which a set of inherent characteristics of an object fulfils requirement (ISO, 2015). Based on the stated definition of quality, it is clear that the basis for defining the quality of service is to determine the characteristics of the service and the needs of the customers. Most often, this process is not easy due to the specificity of the services in terms of tangibility, durable results, quality consistency and customers' needs. Incomplete service makes it difficult to define service quality characteristics as well as to identify customer needs. The durability of the results is based on the memory and the subjective experience of the received service and can be difficult to measure. The stability of the quality of the service depends to a great extent on the competence, kindness, physical and psychological state and other characteristics of the service provider (Filipović and Đurić, 2009). To evaluate the quality of the service, the most commonly used RATER model is defined by Parasuraman, et. al. and represents an acronym of English words Reliability, Assurance, Tangibles, Empathy, and Responsiveness (Parasuraman, Zeithamel and Berry, 1988). The essence of this model is a questionnaire for the customer regarding his expectations and experience of service in relation to 5 quality dimensions (Electronic commerce group, 2017):

- Reliability - the ability to deliver the promised service in accordance with the specifications specified at a specified time;
- Assurance - having the necessary knowledge and skills to perform the service, the confidentiality and honesty of the service provider, safety (no danger, risk and doubt);
- Tangibles - the existence of physical objects, equipment, printed and video materials;
- Empathy - the effort to get to know the customers and recognize their needs;
- Responsiveness - Readiness to help customers get the service at a given moment, availability.

Below, in Table 1, we present an example of a charge service will be shown – the use of Premium lounge.

Table 1: RATER model for the use of Premium lounge

Quality dimension	Characteristic of the service
Reliability	Consistency and availability of offered content
Assurance	Ability to meet customers requirements
Tangibles	Interior design, modern technology and accessories
Empathy	Understanding customers needs
Responsiveness	Availability of staff for the sale of passes and service personnel

This example shows that the use of Premium lounge, for the quality dimension of the participation of tangible products, the characteristics of quality - the appearance of the interior, modern technology and additional equipment - derived from the question: Are the equipment and technology modern?

Through its quality research, previously, Parasuraman has developed a GAP model (Parasuraman, Zeithaml, Berry, 1985), according to which the quality of the service directly depends on the differences between the customer expectations and the achieved performances. It can be said that the quality of the service can be measured by the size of the gap between the expectations of the customer and his experience of the delivered service, that is, the quality of the service is higher if this difference is lower. The starting point for defining the quality of a service is the customer, his needs and expectations. The task of the marketing function is to research, recognize and understand these expectations, and based on that, specifies the quality of the service. The delivered service must correspond to the specified and promised service. The circle is closed by the customer and his perception of services received in the sense of meeting his expectations.

### 3.1.1. Understanding expectations and perceptions of the customers

Customers' expectations are not uniform, and often can not be clearly defined. It depends on the demographic, cultural, social and individual characteristics of the customers, so companies constantly make efforts to better understand and assess the needs and expectations of their customers.

Numerous studies analyze the importance of individual services for customers in the field of air transport. One of them is Hong Kong, where 26 airline services are considered (Gilbert and Wong, 2003). Customers evaluated the importance of services with ratings from 1-8, and the results showed that with the highest rating - of the highest importance for the customer - basic services: safety and accuracy in the order of flight. Additional services such as: the ability to use the Internet and mobile phones, car rentals, hotel accommodation and travel insurance are of the least importance for the customer with ratings below 5. The impact of individual services on the loyalty of the customers was also examined and presented with appropriate weighting using AHP method (0.085), leisure time (0.045), and extended service (0.044) (Tsaour, 2002). It is clear that priority customers provide basic airline services, as well as hospitality and cleanliness, while additional services are of minor importance. Nevertheless, the data on the growth of revenues from additional services and their share in total revenue shows that interest in using these services is rising, and that additional services should always be taken in account.

It is known that the price of a service affects the customer's perception of quality, and therefore his expectations. Therefore, the customer's payment ability also affects the expectations and understanding of the quality of customers. If the customer choose a lower ticket price, he decrease his expectations and accepts less benefits and lower quality. On the other hand, customers who are willing to pay extra service expect all service quality dimensions at a high level.

After receiving the service, the customer summarizes the impressions and forms a subjective attitude about the quality of the service. This attitude also depends largely on the accompanying services whose evaluation makes a difference in the perception of the quality and determines the behavior of the customers in the future in relation to the service and the supplier. The positive perception of the service has a positive impact on the evaluation of the service, customer satisfaction and the image of the airline. If the customers' perception of received service is higher than expected, customer satisfaction will be higher, as well as positive image of the airline, customers will remain loyal to the same company and recommend it to others (Park, Robertson and Wu, 2004).

It can be concluded that, in order to achieve customer satisfaction and loyalty, airlines must completely fulfill and even exceed the expectations of the customers.

### **3.1.2. Business system performance and service quality**

One of the definitions of quality was given by Stout, which showed quality as a relationship between performance and expectations. This means that higher performance results in higher quality (Stout, 1985). The performance of the whole system depends on the performance of all of its parts. The gap model indicates the importance of all the organization's functions in the processes of defining, developing, delivering and monitoring of services, from marketing, research and development, through acquisition and quality, to service delivery. In order to minimize the gap, the system performance has to be raised to the highest level. The process of providing the service of the airline is made up of a chain of processes that relate to one another, and the successful realization of each of them depends on the realization of all others. The process success criteria are effectiveness and efficiency, and they depend on the effectiveness and efficiency of the entire business system. Process management involves clear defining of the activities, resources, and the roles and responsibilities of all employees.

The performance of service based business systems is based primarily on employees' work and their direct or indirect contact with the customer, and the competence, motivation and awareness of each individual is crucial for achieving positive business results.

In order to achieve the consistency of the service - that is, the right of every customer to receive a particular service in the same way at any time, from each employee, safely and efficiently, it is necessary to specify the service as accurately as possible and to respect all the rules and procedures for its delivery. In order to avoid improvisation each airline company develops procedures. One of the techniques for graphic overview of processes and relationships between key factors is process mapping (Mijatović, 2015) which is demonstrated through the process of receiving the request for the transport of a bicycle.

The process of receiving a request for the bicycle transport begins with customer request for transporting the bicycle to the booking service. The service receives a request and imports it in the system that checks the inventory for the received request. If it is available on inventory, the specialist confirms the request; however, if it is not available, the booking service receives information and informs the customer about it. Upon receiving the notification, the customer requests for a second flight. If there is an alternative, it resends the bicycle request and repeats the same procedure, and if there is no other flight, the process ends. Upon confirmation of the request, the specialist for this function checks the compatibility of the requirements with respect to the type of aircraft. If the dimensions of the bicycle correspond to the aircraft type specifications, the specialist confirms the request and informs the passenger about it, and if not, rejects the request and transmits the negative message. Thereby, the process of receiving the request for the bicycle transport ends.

## **4. THE CHALLENGES AND FUTURE OF THE SERVICE QUALITY IMPROVEMENT**

The specificity of the airline's basic service related to flight safety is that it must not vary depending on the carrier. However, the economic crisis, fuel price variations, and many market participants have led to increased differences in supply and prices of additional services. The expansion of the LCC for the past 20 years has increased the competition for airlines that provide a complete service, so they often reduce the number and quality of services included in the ticket price, which leads to additional pricing of additional services. With this in mind, the size of the seat gradually decreases, so today the most extensive economy class seats in the four largest airlines are narrower than the smallest seats offered in the nineties of the last century (Wu, 2014).

On the other hand, companies that are monopolists on certain lines reduce the quality of their services (take off in time), while at the same time raising prices and lowering the quality of additional services because they do not have competition (Mazzeo, 2003). In this way, they provide themselves with great revenue because passengers do not have many options to choose air carriers.

One of the problems with additional services is the insufficient information about the possibilities and the right to use the special services of the airline.

It is estimated that the number of passengers on the global level in air transport is growing by 5% annually, and that in 2020 it will reach a figure of 3.8 billion passengers. It is therefore expected that the sale of additional services will grow. In order to meet the customer needs as fully as possible, in the race with the competition, continuous improvement and improvement of the assortment and quality of services is necessary.

Modern trends in improving the quality of additional services of airline companies are moving in two directions. Companies that base their business strategy on a low-cost model are decreasing their services

by offering passengers a minimum of service and expecting that each individual can subsequently purchase a service of his choice. On the contrary, other companies are specifically focused on adaptability to certain categories of customers. In this regard, they develop special programs in which they combine more services into special packages at lower prices (branded tariffs). Connection of optional services that airlines have previously charged separately as a la carte services with common basic services are defined as branded tariffs. The airline benefit is to increase the sales of additional services, but also to target service packages according to customer requirements. Beside the opportunity to fully satisfy customer needs, the customer benefit is ability to get discount of 10% to 12% on the individual additional. Branded tariffs enable the company's brand recognition and customer loyalty (Macnair travel management, 2017).

An example of a successful company is the Emirates Airlines whose motto is "Flexibility" and which has established high standards for all of its services, is the leader in technological innovations, and provides value-added services that are tailor-made and customer-oriented. Customers of the services of this carrier can do the check-in at the airport - at the counter, in the lounge and on the self-checking machine (Dubai airport) or via Internet and SMS. This company is a pioneer in services - fun and communication during the flight (IFEC - In flight entertainment and communication) (Anwar, Hussein, Moosa and Faris, 2012). The first class offers personal rooms with special benefits, which are considered as luxury and significantly increase the price of the tickets, and will only be chosen by more prosperous passengers. Therefore, most airlines will not include them on their regular flights. However, in order to satisfy the needs of majority, it is advisable to expand the range of services so that each passenger can choose between several options. This does not necessarily have to increase the cost of airlines.

Better customer informing includes: arranged and updated websites, transparent chargeable and unchargeable services, available call centers and provision of complete information by agents. Besides good promotion, it is also necessary to provide feedback from the customers. An unsatisfied passenger will almost certainly appeal to the responsible airline service, while the perception of most passengers will remain unknown to the company. In order to keep track of customer satisfaction, the passengers could fill in a questionnaire during the flight, to show their satisfaction with services. In order to improve and enhance the level of service quality, continuous monitoring and analysis of the results, is needed.

## **5. CONCLUSIONS**

Research incorporates authors' knowledge of quality management and work experience with subject literature. This paper presents additional airlines services (both chargeable and non-chargeable), methods for monitoring their quality and quality management functions of these services. The significance of chargeable services for airline companies is expressed by the economic indicators of the growth of revenues coming from additional services and their share in total revenue. Considering that there is a steady increase in the number of passengers in the air transport, an increase in the sales of additional services can also be expected. Stronger competition, desire for profit and new markets are encouraging airline companies to be creative and introduce new content at affordable prices. At the same time, the development of information and communication technologies is changing the needs, expectations and demands of the customers, and airlines have to adapt and respond to these challenges.

Bearing in mind that the general trend in service activities is customization, airlines will increasingly abandon the concept of universal service and switch to service-oriented models for different target groups. Expectations and customer satisfaction must be constantly monitored and reviewed, and based on those expectations and reviews, airline companies should define and specify the quality of services. All the functions of the organization and all employees must work effectively and efficiently to meet all the goals of the organization and the quality objectives. In regard to this, continuous review and improvement of system performance is also necessary.

The aim of this paper is to point out the importance of quality management of additional services to increase customer satisfaction, resulting in a better image of the airline, retaining existing ones and acquiring new passengers. The focus of the work was on the theoretical considerations of the function and importance of quality management of additional airline services, especially for the purpose of improving quality, and the ultimate effect of this is the creation of benefits for all stakeholders of the process.

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# RISK MANAGEMENT INTEGRATION THROUGH ISO 9001:2015, ISO/IEC 27001:2013 AND ISO 22301:2012 STANDARD REQUIREMENTS

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**Abstract:** *The main purpose of this paper is to indicate how the organization can deal with risks related to quality, information security and business continuity through the coordination of different risk management methods, and to present the importance of risk management for organizations nowadays. We analyzed the requirements of ISO 9001:2015, ISO/IEC 27001:2013 and ISO 22301:2014 related to risk management. This served to create a base for integrating the requirements of the above-mentioned standards into a simple system that helps organizations to examine and continually treat risks is shown through this paper.*

**Keywords:** *risk management, quality, information security, standards, integrated management system*

## 1. INTRODUCTION

The notion of risk, as a situation where the undesired variation from the intended outcome is possible, always exists in our environment, and for the business of today, this situation is inevitable. Risk management is reflected in the systematic prevention of occurrence of harmful events and by undertaking well-directed actions in connection with any business activity, whether financial or non-financial (ISO, 2015 a).

Risk management is an important business activity for companies of all sizes. Implementation of risk control that complies with the requirements of management systems standards is a much easier approach for the organizations. The companies that efficiently manage their risks will much more probably succeed and produce high quality products and services, aligned with its business goals.

Current trends in the field of security and quality management systems are focused on finding solutions that act preventively to losses through efficient and effective tools. Economic crises, migration and globalization have caused constant changes regarding all business dimensions and in that way force management to analyze and manage the risks it recognizes. A risk analysis based on a scientific approach, can be defined as a systematic process with iterations, that implies the assessment and interpretation of accurate information about system analysis and following identified hazards. Implicit results of the analysis, qualitative or quantitative, express the level of risk. The results help us make a decision whether the risk is acceptable or not (Pačaiova, Sinay, Nagyova, 2016).

The fact is that risk management as well as quality management is a 'journey, not a destination', and this road leads to the continual improvement of the business processes, since the creation of the term quality, to the present and in the future (Loosemore, Raftery, 2006). The management system nature is based on Deming's PDCA (Plan-Do-Check-Act) cycle which drives continual development, reviews and improvements of the system. Each review may result in corrective and preventive actions or identification of positions for risk management improvement.

The steps that risk management involves are different authors define through different approaches. For example: setting and defining objectives, forecasting, planning with decision making, obtaining resources, organization, motivation and instruction, realization, coordination, adaptation and learning (Vujošević, 2008); or for example: identification, analysis and risk control (Đapić, Lukić, Kilibarda, 2012).

For the purposes of this paper, the following processes can be singled out for each approach:

- Risk identification,
- Risk analysis and ranking,
- Risk control and
- Risk inspection and monitoring.

## **2. THE RISK CONCEPT IN STANDARDS FOR QUALITY, INFORMATION SECURITY AND BUSINESS CONTINUITY MANAGEMENT SYSTEMS**

### **2.1. The Risk Concept in the Quality Management Systems**

In terms of the ever growing competition on the global market, customer satisfaction is among the critical success factors for the processes related with products and services. The ISO 9000 Standard Series since the first version in 1987 have so far been developed. By collecting numerous examples from business practices, standards are expanded, revised and kept up-to-date. The famous, wise Aristotle's quote: "For the things we have to learn before we can do, we learn by doing", completely describes the development of standards (Soyle, 1994).

In order for the user to always feel that in "safe hands" while using a particular product or service, it is necessary, in addition to the quality of the output product or service itself, to provide continuous stability and inspection of the company's internal organization. One of the cornerstones of safe and continuously business is an effective risk management that makes the quality constantly ensured.

A new version of the International Standard specifies requirements for an organization to understand its own context and to identify risks as a basis for planning. It represents the use of the new concept of 'risk-based thinking' in the planning and implementation of quality management system processes and helps in determining the scope of documented information. One of the key role of the quality management system is to act as a preventive tool (ISO, 2015 b).

### **2.2. The Risk Concept in the Information Security Management Systems**

The fact is that in this so-called. cyberspace happens a lot of undesired events. The important goal of each organization is business safety, which largely depends on the protection of information property, other property and resources. Therefore, the introduction of the information security management system represents the implementation of the necessary actions to achieve a satisfactory level of information security within the organization. The emphasis is on the risk management process that accelerates the selection of preventive and corrective actions and inspections that, if properly implemented, ensure that the system evolves towards a change management system in a safe environment (Kokic, 2016).

The risk in ISO/IEC 27000 is defined as the effect of deviation from the expected and it is indicated by the level of risk that is defined as the relationship between the consequences of the risk and the probability of their occurrence (ISO, 2016). When we talk about the security risks of information, we can notice the three spheres influenced by this management system. These are: information security, information technology security, and corporate (physical) security and protection. The information security refers to all forms of data that an organization has at its disposal. It relies on the classic Confidentiality-Availability-Integrity (CIA) triad for expressing security objectives. The CIA triad was introduced in the Nineties as a multipurpose, standard way to express security requirements regarding information assets (Abdulhadi, Damiani, 2017).

The risk management is according to ISO/IEC 27001:2013 standard presented through clear requirements for risk management and different rules of conduct designed in the form of inspections presented in Annex A of this standard. The inspections in Annex A provide the correct protection and classification of information. This is also achieved through the security of information technologies that includes vulnerability management, incidents, configurations, networks, availability, back-up activities, changes, and everything related to the functional safety of computers and portable devices (ISO, 2013). Corporate (physical) security and protection is a segment that deals with the physical aspects of protection, employee checks, protection against theft, violence, sabotage and any other harmful behavior or situation.

### **2.3. The Risk Concept in the Business Continuity Management Systems**

Business continuity according to ISO 22301:2012 represents the capability of the organization to continue delivery of products or services at acceptable predefined levels following disruptive incident. Business continuity management is defined as holistic management process that identifies potential threats to an organization and the impacts to business operations those threats, if realized, might cause, and which provides a framework for building organizational resilience with the capability of an effective response that safeguards the interests of its key stakeholders, reputation, brand and value-creating activities (ISO, 2012).

Despite the big caution imposed by quality and information security management systems, the hazards still remain present in the organizations. As much as organizations are trying to reduce the risk probability or effects to the acceptable level, those risks continue to exist. If some risk has been identified and especially if



the risk has not been brought to an acceptable level, the probability of occurrence, i.e. the realization of possible undesired outcome, still exists. When a business breaks, organizations are facing with huge financial and reputational losses.

If the interruption of the business is longer, the damage is bigger and more serious. Business continuity management systems emphasizes the need for a well-defined structure of response to incidents. This assures that when incidents occur, there are prepared plans that define the responsibilities and concrete actions that the responsible persons must undertake in order, to return the system to the normal state of functioning. Depending on which interested parties, incidents have an impact, appropriate communication schemes are also defined in times of crisis, for example with the public or state authorities (Tangen, 2012).

### 3. MANAGEMENT SYSTEMS STANDARDS' REQUIREMENTS RELATED TO RISK MANAGEMENT

Standards can generally be viewed as the 'best practices' of management in some business areas, resulting from the experience of dissimilar companies with different environments and conditions, as well as detailed analyzes and requirements imposed on the market. Standards are designed to represent a set of requirements or guidance that organizations need to conform to or follow, in order to achieve the appropriate level of regulation of their business functions, such as quality management, information security, environmental protection, compliance, anti-bribery etc.

The latest versions of the management systems standards are accordance with the Annex SL High Level Structure and recommendations. According to this document, the standards must contain the scope, normative references, terms and definitions, and requirements relating to:

- Context of the organization,
- Leadership,
- Planning,
- Support,
- Operation,
- Performance evaluation and
- Improvement.

Through most of these groups it requires standards, which is especially noticeable in ISO 9001:2015, those who are related to risks are intertwined, which will be presented in this chapter of work.

#### 3.1. Requirements Related to Risk in the Quality Management Systems Standard

In the ISO 9001:2015 standard, requirements related to risks and opportunities are intertwined across all clauses of the standard to a greater or lesser extent. Below are the locations in the standard that mention the risks:

**Table 1:** Requirements related to risk in the ISO 9001:2015

Clause	Title	Description
0.3.3	Introduction	▪ Describes the concept of risk-based thinking.
4	Context of the organization	▪ The official request for actions concerning risks and opportunities is directly addressed to this point.
5	Leadership	▪ It is required to promote the concept of risk-based thinking throughout the organization by the top management. ▪ It is required to determine the risks that affect the conformity of the product/service by the top management
6	Planning	▪ The organization is required to consider issues relating to the context and interested parties, and in accordance with that, determine the risks and opportunities to deal with, as well as to apply and evaluate the effectiveness of risk-related actions.
7	Support	▪ The organization is required to identify and provide the necessary resources, taking into account the inherent risks and limitations.
8	Operation	▪ It is required to apply actions to prevent human fault.
9	Performance evaluation	▪ It explicitly requires the establishment of actions relating to risks and opportunities.
10	Improvement	▪ It is required that the organization, if necessary, again review and update the risks and opportunities it identifies.

Requirements 4 and 6 represent the most important risk-related requirements. In Clause 6 – *Planning* specify that the organization must plan risk-related actions, however, there are no requirements relating to formal risk management methods or a documented risk management process. The organization is responsible for the implementation of its *risk-based thinking* and for the actions that it undertakes to deal with risk, including whether it keeps or does not keep documented information as evidence of its risk assessment.

The Clause 4 entitled ‘*Context of the organization*’ is another novel concept in the new version of the standard for quality management systems. We note that before the requirements are complied with, at the very beginning of the reading of the requirements of the standard, there is a need to identify the organizational environment, but also all internal issues. Also, at the outset, it is necessary to identify all the interested parties that have an impact on the organization, in order to meet their requirements faster and faster. To apply this requirement, there are multiple methods, the choice of which, depends on the type and size of the organization.

In the light of fulfilling requirements about Context of the organization must identify internal and external issues that may affect the effectiveness of the quality management system. This means that these issues are subsequently used for the purposes of defining actions that address risks and opportunities.

### 3.2. Requirements Related to Risk in the Information Security Management Systems Standard

Standard ISO/IEC 27001:2013 is developed as a set of requirements, which are very similar to those for quality management systems due to the compliance of the Annex SL. Many clauses have the same title as the ISO 9001:2015 standards’ clauses, but they refer to the consideration of these topics in terms of information security. Also, besides the requirements (clause and subclauses), there is a Annex A with a large number of inspections related to information security. Below is a summary of the ISO/IEC 27001:2013 related risks (ISO, 2013):

**Table 2:** Requirements related to risk in the ISO/IEC 27001:2013

Clause	Title	Description
4	Context of the organization	<ul style="list-style-type: none"> <li>▪ Determining internal and external issues relevant to the information security management system refer to ISO 31000:2009 for risk management systems;</li> <li>▪ The organization is required to identify interested parties relevant to the information security management system.</li> </ul>
6	Planning	<ul style="list-style-type: none"> <li>▪ It is required that the organization defines and applies the risk assessment process for information security;</li> <li>▪ It is required that the organization defines and applies the risk-based process for information security based on the results of risk assessment.</li> </ul>
8	Operation	<ul style="list-style-type: none"> <li>▪ It is required that the organization defines and applies the risk-based process for information security based on the results of risk assessment.</li> </ul>
	Annex A	<ul style="list-style-type: none"> <li>▪ Inspections and goals related to documented information, information technology and physical security.</li> </ul>

Clause 4 - *Context of the organization* is very similar to that of ISO 9001:2015, while clauses 6 - *Planning* and 8 - *Operation* are the remaining clauses that mention risks, by requiring a clear process of assessing and handling risks that are not explicitly exist in ISO 9001:2015.

Assessed and analyzed risks should be compared with those inspections and their objectives from Annex A and link them with the impact on the relevant information property that the organization owns. If the identified risk coincides with one of the inspections or can jeopardize the realization of any of the stated objectives, the actions to mitigate this risk must include all those standards specified in this inspection. In other words, the action will include at least the one that requires the appropriate inspection in Annex A.

### 3.3. Requirements Related to Risk in the Business Continuity Management Systems Standard

Although ISO 22301 also has the structure prescribed by the Annex SL and a large number of the same requirements as the previous two analyzed standards, it is important to note the requirements related to risks that this system will emphasize in an integrated management system. The most specific requirements that complement the risk management projection in relation to ISO 9001 and ISO/IEC 27001 are contained in the

Clause 8 - *Operation*. These requirements, as well as other generic requirements in which the aspects of business continuity are stated, are explained in the following table (ISO, 2012):

**Table 3:** Requirements related to risk in the ISO 22301:2014

Clause	Title	Description
4	Context of the organization	The organization is required to identify interested parties relevant to the business continuity management system.
5	Leadership	Management must demonstrate its commitment by participating in: <ul style="list-style-type: none"> <li>– defining the criteria for accepting risks;</li> <li>– testing of Business Continuity Plans;</li> </ul>
8	Operation	This clause of the standard explains in detail that it is necessary: <ul style="list-style-type: none"> <li>– implement an impact analysis on business;</li> <li>– implement risk assessment and ranking;</li> <li>– define a business continuity strategy based on the results of the impact analysis of threats to business, as well as to provide all necessary resources for the implementation of this strategy, and then implement actions that reduce the probability of termination of business, shorten the interruption period or limit the termination of business;</li> <li>– establish procedures and Business Continuity Plans that respond to potential incidents and business disruptions;</li> <li>– implement regular testing of Business Continuity Plans.</li> </ul>

It is particularly interesting to point out that the inspection A.17 *The aspects of information security* in business continuity management in Annex A of ISO/IEC 27001:2013 is very familiar with this standard because it requires information security continuity to be embedded in the organization's business continuity management systems. This inspection further requires: planning the continuity of information security, implementing the continuity of information security through appropriate processes and documented information, and conducting verifications, reviewing and assessment the continuity of information security (ISO, 2013).

#### 4. RISK MANAGEMENT INTEGRATION

How to start the implementation of the management systems and how to integrate multiple management systems at once? The answer to the question is an *integrated management system*. The preceding chapters of this paper have analyzed the requirements of the standards for quality management systems, information security and business continuity. Although all these standards are the same in structure, we paid attention to the places with emphasis on risk management i.e. which requirements related to risks are specific to ISO 9001, ISO/IEC 27001 and ISO 22301.

Integration of the management systems implies the upgrade of one management system with another, precisely those aspects that are unique to that management system. The essence of this paper is the integration of risk management in standardized management systems, and in this chapter, based on the analyzed requirements of three standards for management systems, will be presented the way in which risk management can be applied in the organization of any type, so that it meets the requirements of the three International standards.

The following are the aspects that need to be addressed in the implementation of risk management, in accordance with the requirements of ISO 9001:2015 for quality management systems, ISO/IEC 27001:2013 for information security management systems and ISO 22301:2012 for business continuity management systems:

**Table 4:** The main aspects of risk management for integration of standardized managements systems

ISO 9001:2015	ISO/IEC 27001:2015	ISO 22301:2012
Context of the organization	Context of the organization	Context of the organization
Risk-based thinking	CIA triad	Implementation of Business Impact Analysis
Risk consideration related to interested parties and stakeholders	Evaluation of probability and consequences of risks	Implementation of business continuity strategy
Risk consideration related to processes	Application of risk treatment plans and inspections from Annex A	Implementation of Business Continuity Plans

We can see that the basis for integration is to determine the context of the organization, in particular, its internal and external environment and interested parties in relation to quality, information security and business continuity. If we look at risk management separately from the implementation of the overall management system, it can be said that establishing the context of an organization is the starting point of the risk identification step.

It can be noted that when the requirements of the ISO 9001:2015 standard are fulfilled, the risks remain only upgraded by looking through information security and business continuity, by evaluating their likelihood of occurrence, consequences and impact on business, defining the way of risk treatment, and determining special treatment of risks that jeopardize the continuity of business and determine the manner in which it is handled if the risks are realized. In the continuation of this chapter, analyzes are proposed that can support this way of integrating risk management.

#### 4.1. Implementation of Integrated Risk Management

**Risk identification** is the initial and at the same time the most difficult phase of risk management. As an initial method of identification, a *brainstorming* method can be used to identify the risks, associated with the quality, effectiveness, and efficiency of the implementation of the process, together with the owners and executors of the process. In the identification step, it is important to generate as many ideas as possible regarding potential unforeseen situations, whether they have already occurred or are likely to occur, by looking at the results of the SWOT and PEST analysis, but also by using benchmarking. Sometimes it is difficult to identify risks related to information security and business continuity without a person who has expertise in those fields, and in that situation as a help we can use, a risk assessment matrix created and filled out by an expert for information security. For identifying risks related to business continuity, consultations with the physical-technical protection manager, corporate security specialists or employees in charge of evacuation and fire protection are needed in order to define general business continuity risks.

**The step of risk analysis and ranking** usually consists of assigning a qualitative description or quantified value to the identified risks. The risk analysis is the fundamental of the FMEA method. This method represents structured approach to risks and thus helps system designers understand the outcomes and priorities even before the formal completion of an analysis risk (Jenab, 2015). FMEA analysis is often used to detect possible causes of a technical and technological nature, but has recently been recognized as suitable for the analysis of the cancellation of various types of systems related to the providing of services. If there is any system like the quality management system, FMEA analysis can be applied. In the risk analysis step, it is most important to clearly identify the scope and significance of risk assessments in order to obtain as precise results as possible. In this step, it is also possible to join the Business Impact Analysis by looking at its results and deciding what needs to be done as an activity to combat these risks.

**Risk control** should answer the following questions: How can positive effects be strengthened? How to reduce or prevent unwanted effects on the desired result? The management of the organization should determine how to deal with the analyzed risk, i.e. which risks will be accepted and for which they will define and implement certain actions for their suppression. For risks related to the security of information, according to the requirements of the standards, it is necessary to develop Risk Treatment Plans, and for the risks that cause a business stoppage, it is necessary to develop and regularly test the Business Continuity Plans.

**Risk inspection and monitoring** should respond to the question of how the organization evaluates the effectiveness of the actions undertaken in the risk control phase and how the organization can achieve continuous improvement in risk treatment. It is precisely this step that relates to the identification of new and reevaluation old risks in order to assess the effect of the conducted action and, if necessary, define additional or correct the already established actions. The following is an overview of a possible combination of tools and methods by which integrated risk management can be applied:

**Table 5:** Useful tools and methods for the implementation of integrated risk management

	<b>Quality management system</b>	<b>Information security management system</b>	<b>Business continuity management system</b>
<b>Risk identification</b>	SWOT, PEST(EL), Brainstorming, Benchmark	SWOT, PEST(EL), Brainstorming, Benchmark,	SWOT, PEST(EL), Brainstorming, Benchmark,
<b>Risk analysis and ranking</b>	FMEA worksheet (analysis)	FMEA worksheet (analysis)	FMEA worksheet (analysis) Business impact analysis
<b>Risk control</b>	FMEA worksheet (actions)	FMEA worksheet (actions) Risk Treatment Plans	Business Continuity Plans

<b>Risk inspection and monitoring</b>	Monitoring the implementation of the actions from the FMEA worksheet (actions); restarting the risk identification process	Monitoring the implementation of the actions from the FMEA worksheet (actions) and implementation of the Risk Treatment Plans and their correction; restarting the risk identification process	Monitoring the implementation of Business Continuity Plans; restarting the risk identification process
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## 4.2. Obstacles for Implementation of Risk Management

Until we achieve the benefits of risk management integration, many problems can arise during its implementation. When we talk about the information security management system, there are many aggravating occasions for its effective implementation. It often happens that there is a lack of expertise and competencies, necessary to deal with information security at all hierarchical levels of the organization, while imposing constant changes in the form of restructuring, merging organizations, various acquisitions and alliances. Each of these changes has a major impact on the security of information (Asheden, 2008).

In order for organizations to understand the importance of dealing with risks at all, it is necessary to create an appropriate internal culture, that is often very difficult to achieve. It develops in line with the behavior of employees and their awareness of risks, in the same way that organizational culture develops in accordance with the behavior of employees in the organization. It is based on the interaction of employees with information property and the safe behavior they implement in the context of organizational culture. For the purposes of this paper, a culture of risk is defined as habits, assumptions, principles, values and knowledge that employees and stakeholders have in interaction with the organizational system and procedures at any time. From interaction arise acceptable or unacceptable behavior (e.g. incidents). The culture of risk and information security comes in time (Da Veiga, Eloff, 2009).

Of course, for many organizations there is a problem of lack of time for systematic risk management, resulting in misinterpretation of risk management at different hierarchical and organizational levels.

## 4.3. Benefits of the Implementation of Risk Management Integration

Implementation of a quality management system requires the organizations to plan their steps carefully with consideration of all factors that can disturb efficient business processes and thus reduce the quality of final products and services. Implementation of the information security management system improves the quality of the information system and information security in general, and raises awareness of safety among employees, customers, suppliers, etc. It also contributes to a better integration of information technology with business (Pelnekar, 2011).

The business continuity management system assures that organizations are always ready for a quick response and return to operational conditions if incidents that have interrupted business happen. Planning and testing of Business Continuity Plans are the activities that employees learn to react in emergencies, and therefore, they more easily handle crisis situations.

If an organization wants to benefit more from the management system, it should understand that their implementation is influenced by the business strategy, the size and structure of the organization, the environment and changes in the environment as well as the risks that arise from the organization's internal and external environment (Kaziliunas, 2012). Thus, the risk management integration related to quality, information security and business continuity gradually becomes part of every business segment.

The principle of risk-based thinking becomes part of everyday activities, different projects, organizational changes and control over any type of resource. This means that employees become aware of the risk of the listed business segments in relation to quality, information security and business continuity. In this way, activities and resources are protected, while barriers that can deter organization from reaching set goals are considered.

## 5. CONCLUSION

We can conclude that risks have become one of the key roles of business quality. After considering the notion of risk management from different sides, risk management steps are presented, which are very close to the fundamental management steps and the famous Deming PDCA cycle.

Meeting the requirements for quality management systems standards creates the fundamental for upgrading the system to the aspects of information security management. By analyzing the requirements of the

standards for Information security management systems it can be concluded that they can easily be complemented by requirements for Business continuity management systems. This provides an indication of how the risk management required by these three standards can be integrated into an effective and efficient system by selecting appropriate tools and methods for its implementation. The FMEA method is proving to be very efficient and effective when used with other tools such as SWOT, PEST, brainstorming, benchmarking, Risk Treatment Plans for Information security and Business Continuity Plans.

The initial point of the quality management system, information security and business continuity (as well as other management systems) is *the context of the organization*, which examines everything on which the business of an organization is based and what it surrounds. With a higher level of integration of the quality management system, information security and business continuity, a modern framework for safe and secure business is being created.

Organizational culture based on awareness of the importance of security and safety, will reduce the risks to quality, information, bad behavior and harmful interaction with information property and inadequate handling in emergencies. It is necessary to present the first effects of such a system in the right way to the employees. Once employees understand that risk management is not a burden, but simply helping to raise their daily work to a higher level, then it is possible to talk about the effective implementation of risk management.

By cyclical repetition and continuous improvement of actions and methods, we have proved that risk management is a 'journey, not a destination'. Risk management is to be 'built-in' in every business process, and it teaches employees to think ahead, which speaks of its necessity for business. By integrating the requirements of standards for quality management systems, information security and business continuity, a holistic system is provided that is capable of predicting and responding to an organization of any kind on the risks that can occur inside or in its surroundings.

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# THE SOFTWARE IMPLEMENTATION OF THE PROTECTION MEASURES OF INFORMATION IN THE BANKING INFORMATION SYSTEM

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**Abstract:** *The ISO 27001 standard is a significant standard for organizations dealing with services in areas that are related to Information Technology and the need to preserve confidentiality of information. Implementation of the system of protection and security of information provides conviction to the clients and business partners of the organization to be accountable according to the information. Examples of organizations that pay tremendous attention to data security, and in which the ISO 27001 standard is applied, are banks and other financial organizations. This paper deals with the software implemented measures for ensuring data security and the original privacy protection measures for users of the bank's information system.*

**Key words:** *ISO Standard 27001, Information security management system (ISMS), Security Information, User privacy protection, The Banking Information System*

## 1. INTRODUCTION

Information security is becoming increasingly important in modern society. Modern state and business entities are increasingly dependent on information and communication infrastructure that allows the flow of large amounts of information between entities, thus providing information and information systems to numerous attacks and abuses. The concept of security of information includes the following types of protection measures:

- Technical protection measures - use passwords, encryption, access rights, network security, and more;
- Administrative protection measures - include security policies, bylaws, procedures harmonized with laws;
- Physical protection measures - include video surveillance, room protection, physical access control;
- Organizational measures - include the division of duties and responsibilities for security, and for human resource management, and others.

All these protection measures include the ISO 27001 standard. When talking about this standard, information is primarily meant as they represent the core business of the largest number of companies in the present day. Information can be created and used in various forms: written on paper, in electronic form, sent by class mail or by electronic means, mentioned in the conversation, and the like. Information protection is necessary because there are threats to information assets from various sources. These sources of threat may be internal, external or incidental, and increasingly threats arise from the abuse of new powerful technologies. Exactly the ISO 27001 standard offers the ability of the organization to effectively and efficiently manage risks due to the likelihood that a threat will exploit existing information system problems and do damage.

Organizations that provide their services using information technology are undoubtedly interested in the ISO 27001 standard. Banks, insurance companies and other financial institutions are the real example of organizations whose business activities have IT support. In addition to physical, organizational and administrative measures that imply the ISO 27001 standard, it is obvious that, due to financial information in the banking information system, banks will be most interested in the application of measures to protect this information that the software should provide.

In this paper, attention will be given to software implemented measures to achieve the security of financial information, as well as to protect the privacy of the users of the information system of the bank.

## 2. ISO STANDARD 27001 AND SECURITY INFORMATION

In the era of current information technologies, information is not only easily accessible but also very "vulnerable". This particularly applies to information of a confidential nature. Today, when almost complete business, from production organizations to banks, is done through specialized information systems, information security becomes very important. In accordance with the security of information, a whole series of ISO 27000 standards are developed that closely define requirements, methods, controls and processes

processes and activities related to the security of information within the organization. In addition, ISO 27001 is one of the most important standards in this series because it defines the requirements for the Information Security Management System. As such, it is applied in all organizations that want to provide their information systems and information for which their security is guaranteed.

Benefits and advantages that the organization can achieve by implementing the ISO 27001 Information Security Management System are:

- evidence of compliance with the requirements of ISO 27001;
- compliance with the best practice of risk management, in accordance with ISO 31000 and ISO 27005;
- Compliance with laws;
- establishing a framework for systemic protection of information resources from malware software, computer abuse, cybercrime and other negative impacts;
- improving credibility among staff, clients and partner organizations;
- the financial benefit of returns through investment in information security;
- Improving the sales of services by raising the level of customer confidence;
- practical decisions relating to security techniques and development solutions;
- the existence of responsibility for the security of information in the organization by all and at all levels;
- better market opportunities by introducing a safer environment for customer data and the knowledge that the organization is exposed to competent assessment.

The official name of the ISO 27001 standard is ISO / IEC 27001: 2013, and in Serbia the official name is SRPS ISO / IEC 27001: 2014. The standard is part of the 27000 series. ISO 27001 is an international standard that relates to the protection and security of information. The Standard provides a comprehensive framework through which an organization identifies, analyzes and addresses security risks of information and ensures compliance with security arrangements in order to keep pace with changes in security threats, vulnerabilities and business impacts. ISO 27001 provides the framework that is necessary to create a secure system. The ISO 27001 compliant system will provide a systematic approach to identify and combat the full range of potential risks to which the organization's information is exposed. It defines four main areas of the information protection system with its requirements:

- Information Security Management System (ISMS)
- Responsibility of the management
- Rating of the management
- Improving the ISMS.

ISO 27001 is a specification of the information management system (ISMS). ISMS is a framework of policies and procedures that includes all legal, physical and technical controls involved in the organization's risk management processes. According to his documentation, ISO 27001 was developed to "provide a model for the establishment, implementation, operation, monitoring, review, maintenance and improvement of information security management systems". ISO 27001 uses a top-down, risk-based approach and is neutral in technology. The specification defines a six-part planning process:

1. Defining a security policy
2. Defining the ISMS scope
3. Conducting a risk assessment
4. Management of identified risks
5. Selecting the control objectives to be implemented
6. Preparing a statement of applicability.

The specification includes: documentation details, management responsibility, internal audit, continuous improvement, and corrective and preventive action. Standard requires co-operation between all parts of the organization. The ISO 27001 standard is comprehensive because it treats information security from three aspects:

- informatics - analyzing and defining the performance of IT equipment, access rights, encryption, passwords, protocols, policies from the point of view of risks to data and information security;
- administrative - defining clear instructions, policies and procedures for generating information, their distribution, storage (storage);
- physical - physical access control, employee records, video surveillance, workstation protection.

The Standard treats information as asset and provides basic guidelines for its preservation, safe management and use. Like most other standards, it is compatible with ISO 9001 but specifies additional requirements for identifying information security risks and establishing mechanisms to eliminate or reduce them to an acceptable level. Implementation of the system of protection and security of information provides conviction to clients and business partners to act responsibly according to information and to use them and distribute them professionally and safely.



ISO 27001 is also compatible with ISO 22301: 2012, in Serbia officially SRPS ISO 22301: 2014 - Social Security - Business Continuity Management Systems - Requirements, which refers to the identification of potential threats per system and which through the established business continuity management system aims to protect the company from potential threats, reduce the likelihood of termination of business, prepare for adequate response if it comes and provide appropriate recovery plans. The incidents covered may range from the sudden break of the IT system to natural disasters and terrorist attacks.

### **3. UTILIZATION OF STANDARD ISO 27001 IN THE BANKING INFORMATION SYSTEM**

The ISO 27001 standard applies in various areas where there are different processes in the organization that are related to security management control such as: security policy, security of organization, control and classification of resources, staff security, security of material goods and the environment, operational management and communication, access control, development and maintenance of various systems and business continuity management. ISO 27001 can be implemented in any organization, profit or non-profit, private or state, small or large. It was written by the world's best experts in the area of information security and prescribes a methodology for the application of information security management in an organization. The organization receives a certificate or certificate that the organization has implemented information security in accordance with ISO 27001.

The ISO 27001 standard is important for organizations that rely on information technology in their business. In these organizations, the basic goals of introducing standards are:

- continuous availability of IT equipment and communications
- protection of information from unauthorized access
- protection of data from loss
- protection against leakage of information
- to ensure business continuity and provision of services in the event of an unforeseen event.

Information protection through the ISO 27001 standard will enable organizations: establishing correct account settings, controlling access to information, controlling network services, securing personal data protection, and securing media protection with transit data.

Implementation and application of ISO 27001 standards allow for better cooperation with similar organizations around the world operating under this model. This standard of organization demonstrates to its users and other stakeholders that they work with business processes based on the principle of security and that business policy is focused on continuous improvement in the information management system and the services related to its services. The benefits of the organization are reflected in the following:

- competition advantage
- reducing the risk of damage and loss of information, and therefore costs
- compliance with applicable legal regulations
- greater confidence of clients, employees, associates, institutions and all stakeholders due to the knowledge that their data is safe
- the existence of responsibility for the security of information by all and at all levels of the organization.

Implementation of the system of protection and security of information provides conviction to clients and business partners to act responsibly according to information and to use them and distribute them professionally and safely. For all these reasons, the ISO 27001 standard is applicable in banks and other financial institutions.

Due to the specific financial nature of the majority of the data in the information system, huge attention is paid to the security of data in both data transmission and access to data and their modification. Priority information security measures in the bank relate to security measures such as encryption of information, regulation of data access rights, network security and others, but at the same time implies the implementation of administrative, physical and organizational measures. The Assembly of the Republic of Serbia, by harmonizing Serbia's legislation with the legislation of the European Union, adopted a set of laws related to information security:

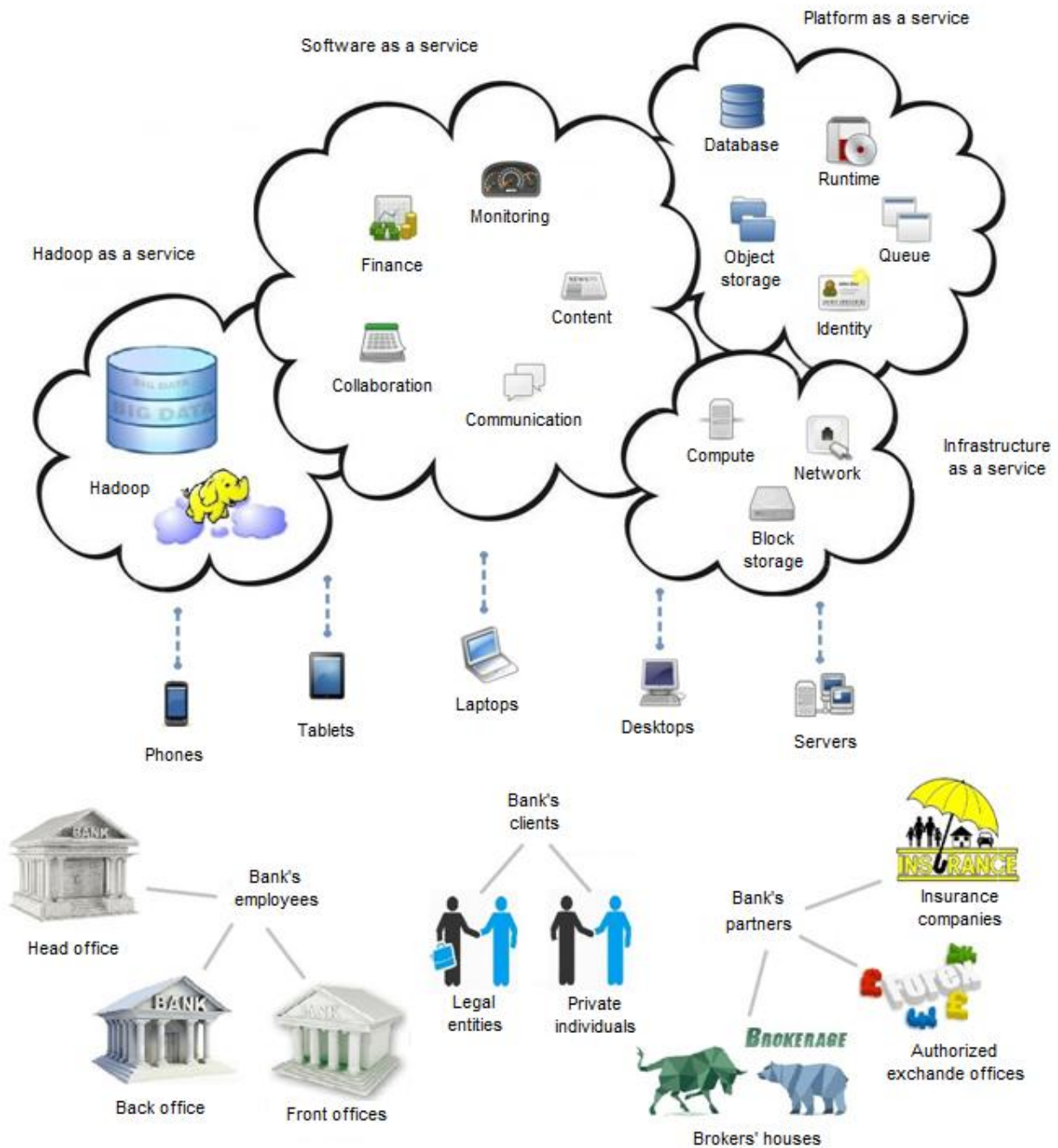
1. The Law on Personal Data Protection
2. The Law on Secrecy of Data
3. The Law on the Keeping of Business Secrets.

In accordance with the Law on Secrecy of Data, the Government of the Republic of Serbia adopted a Decree on special measures for the protection of classified information in information and telecommunications systems. Article 10 of this Regulation explicitly states that in order to maintain the security of the system during its use, the public authority or legal entity shall implement the implementation of new technical and

program resources in the system in accordance with the relevant technical standards SRPS ISO / IEC 27001. Therefore, information protection is in accordance with the ISO 27001 standard, and the basic and most reliable way of implementing information security measures in the bank is just programmatic.

#### 4. THE SOFTWARE MEASURES TO PROTECT INFORMATION IN THE BANK INFORMATION SYSTEM

Software solutions for data protection measures follow the modern accelerated development of information technology. The most up-to-date solution for the platform model of the Bank's information system is Hadoop in Cloud, Hadoop as a cloud service.



**Figure 1:** Hadoop in cloud as a solution for an IT banking platform

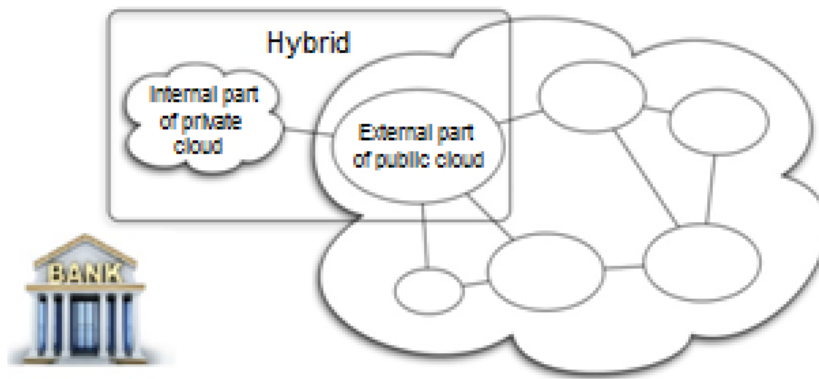
Hadoop Cloud technology ensures the placement of large amounts of data in cloud computing clusters as well as rapidly distributed processing of these data, with software and infrastructure and platforms in the remote cloud of the provider, i.e. vendor. With the appropriate infrastructure in the cloud, users come to

access the information system in a modern way using smartphones, tablets, laptops and other modern devices. The customers in the bank are: bank clients (legal entities and private individuals), bank partners (insurance companies, brokers, authorized exchangers and others) and bank employees - at front offices, back office and bank management (head office) A cloud cloud with services as an IT platform for the bank's information system is given in Figure 1.

If the Hadoop in the cloud is selected as the IT platform solution in the bank, it is necessary to consider also which cloud model to decide - for a public, private or hybrid model. Choosing a cloud model also means ensuring data security and user privacy. The decision on the choice of cloud models is made by a commission comprised of representatives of the following organizational parts of the bank:

- Executive Board
- Information Systems Division
- Department of Security
- Department of Legal Affairs
- Financial Division.

Bearing in mind the financial nature of data in the banking information system and even that most important data should be stored privately in the bank, and also having in mind that due to the need of users of some application can be publicly available to the clients of the bank, it is undoubtedly that the hybrid model cloud a solution for choosing a cloud model. The hybrid model will integrate the internal part of the private cloud of the bank in which the important bank data is located, and the external part of the public cloud in which certain client applications will be specified. The merging of these two parts is shown in Figure 2.



**Figure 2:** Hybrid cloud as a choice of cloud models for the banking information system

The business data model in the bank implies the following data groups:

1. Clients
2. Organizational structure and employees
3. Market data
4. Segmentation and rating of clients
5. Loans
6. Accounts
7. Collaterals
8. Derivatives and Repo
9. Limits
10. General Accounting and Profits & Losses
11. Cash flow
12. National and international payments
13. Security
14. Financial information
15. Regulatory reports.

These data are allocated to the internal part of the private cloud and to the external part of the public cloud, and the allocation is under the responsibility of the Finance Department. Obviously, for example, data from all bank strategies will be secure in private cloud, for example. data on the bank's product sales campaigns for customers will be secure in the public cloud. Data groups are deployed in the confidentiality classes defined by the Department of Security. Based on the confidentiality class, it is known which data is stored in a public cloud, and which is in a private cloud. The confidentiality classes are: (1) Public data, (2) Internal data, (3) Confidential data and (4) Strictly confidential information. Preservation of data security and user

privacy is regulated by program implementation of measures for achieving data security and privacy protection of users.

#### **4.1. Data security**

Data security is achieved by program implementation of data encryption when data is transmitted, when the data is made by the data transmitted from the bank to the cloud and from the cloud to the user, both in reverse and in data restraint, at the following levels: the application level, the level of the Hadoop Cluster, and the file level, i.e. level Hadoop Distributed File System (HDFS).

Data encryption uses different algorithms from simple to cryptographic algorithms such as:

- Symmetric algorithms
- Asymmetric algorithms
- Cryptographic functions for compression - hash functions
- Digital envelope, digital signature, digital stamp and digital certificate.

#### **4.2. User privacy protection**

Users' privacy to access cloud applications would be provided by introducing programmatic measures such as, for example:

- authentication of bank clients when using applications via the Internet;
- assigning passcode to the bank partners (brokers, authorized exchangers, authorized appraisers from insurance companies and others) for authentication during Internet access to the information system;
- Authentication of employees both at the level of the operating system and at the level of each application from the information system.

### **5. THE INFORMATION SECURITY IN THE BANKING INFORMATION SYSTEM**

Information security should also be provided when storing data while transferring a transfer between the bank and the cloud, and vice versa. Significance depends on the following information properties that are also requests for information:

1. confidentiality
2. integrity
3. availability
4. authenticity
5. intolerance
6. authorization.

There are three general categories of cryptographic algorithms that are used today in database systems - symmetric algorithms, asymmetric algorithms, and hashing algorithms, and a more specific category of hybrid algorithms: Digital envelope, digital signature, digital stamp and digital certificate. Symmetric algorithms use the same key both for encryption and decryption of data. Equivalent names for symmetric algorithms are: conventional, secret key, classical, and private key algorithms. The most well-known symmetric cryptographic algorithms are Data Encryption Standard (DES) and Advanced Encryption Standard (AES). Unlike secret keys with one shared key, asymmetric algorithms use two keys. One of the keys is public and other secrets. These algorithms are also called public key algorithms, and their operating principle is as follows: based on the secret key assigned by the recipient, a public key is generated. Known as cryptographic asymmetric algorithms are: RSA, ElGamal, i Diffie-Hellmann.

Cryptographic functions for compression - hash functions are categorized into cryptographic algorithms without a key. Hash function denotes a function that compresses an array of data of arbitrary length into a fixed-length data set. Hash functions are used to protect the integrity of the data and work on the following principle - when the new data is received, it is hashed and then compared to the original hash value. The hash function is used as an accessory, for example, when saving passwords in the database. The famous hash algorithms are, from the older ones - SHA-1 and MD5 algorithms, and the newer ones - SHA-224, SHA-256, SHA-384, and SHA-512. Given which data is encrypted and at what level encryption is performed, there are different types of encryption that are applicable in the protection of the database system, and accordingly the following division:

- encryption for data protection during transmission
- encryption for data protection during hibernation:
- encryption at application level
- encryption at the database level
- encrypting the file.

Data encryption during transmission protects data on the way from bank to cloud and from cloud to user, and vice versa. Data transfer is done via the Internet or via wireless networks. Encrypting data during transmission is necessary to prevent the content of the message after the interception of traffic is detected. This encryption type is most used in data protection since it does not bind to applications and requires minimal development efforts. There are different security protocols for this type of encryption, such as: SSL (eng. Secure Sockets Layer), TLS (eng. Transport Layer Security) and IPSEC (eng. Secure Internet Protocol).

Encrypting data that is idle is the encryption of information in warehouses, i.e. clusters of computers. In this case, there are three most commonly accepted encryption methods: at the application level, at the database level, and at the file level. An example of the most basic protection of information by software at the application level is data masking. Banking ISs usually mask the amounts, bank identification numbers of the bank's clients, their card numbers and others. In Figure 3, a screen display is displayed on which the client card numbers are masked. The procedure for masking the card numbers is software solved by placing six '\*' characters from the seventh position in card number data. In Figure 4, there is a screen display of the application where the amount for the premium client is masked. The masking of the amount is software implemented by setting the black color for the color field property for the amount.

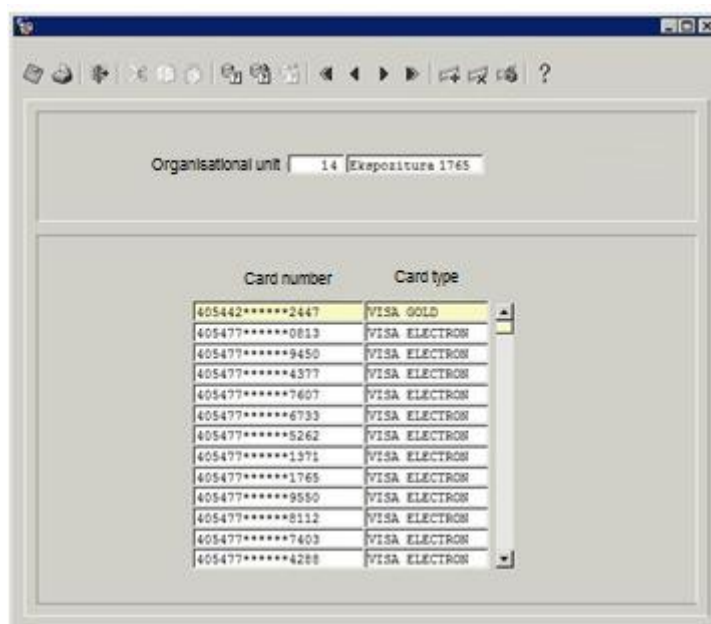


Figure 3: Standard masking the data Card number in banking information system

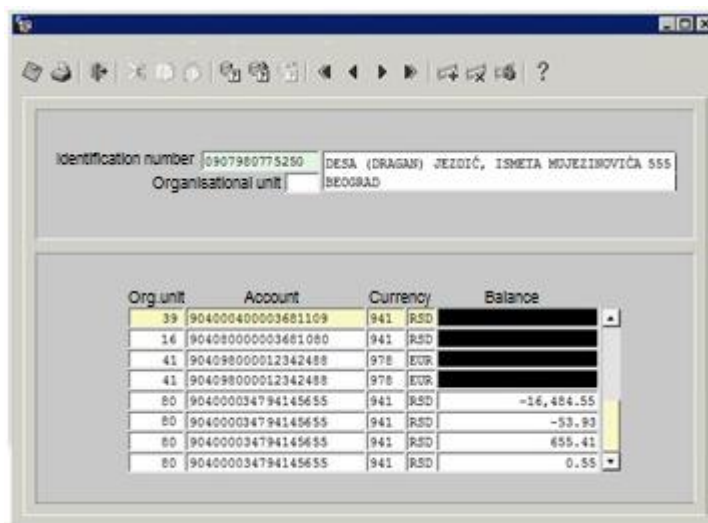


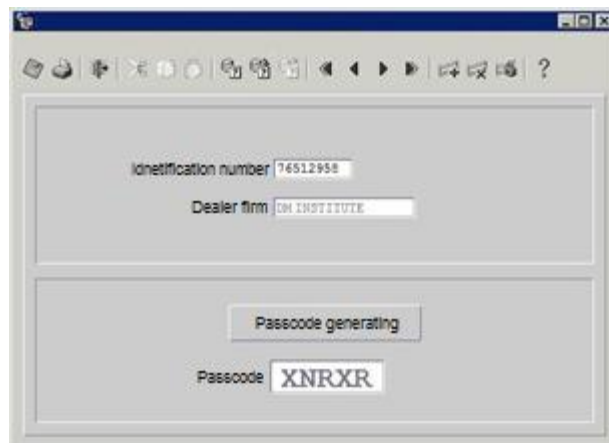
Figure 4: Standard masking the data Balance in banking information system

## 6. PROTECTION OF USERS' PRIVACY IN THE BANKING INFORMATION SYSTEM

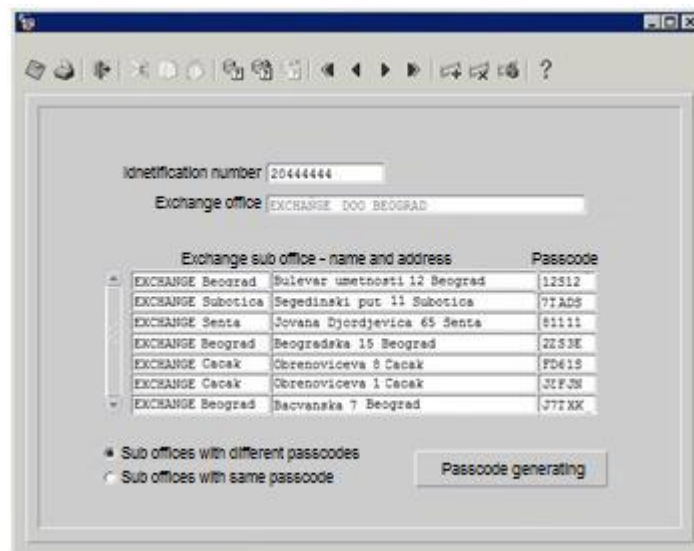
The users of the bank's information system are bank clients, bank partners and employees of the bank. The policy of access control to the system over the Internet, in terms of user recognition, is realized through software implemented user authentication. Each user is embedded in a unique client record. When tricked, the user gets a unique combination of two data code and password, which he can later change in the system. User authentication is accomplished by a program test whether the combination of these two data, which the user has entered, is the same as an existing combination in the system. If it is, it is considered that the authentication is successful and the user is identified by withdrawing his name from the client's records, otherwise authentication is considered unsuccessful. Further work of users in the information system is done in accordance with the set of privileges it has to perform banking activities.

Interesting is the additional authentication of the bank's partner when they access information in the bank by telephone by interviewing a bank employee. In this case, for reasons of safety, measures are taken to record a telephone conversation and program the user's recognition by the employee. This situation occurs in the bank every morning on a business day, when authorized exchangers and partner companies who perform dealer business and who use the money from the bank's vault for these jobs, contact the employees in the bank, ie the dealers in the bank, and ask for a sales course and a purchase the rate that the bank has internally adopted for the current day.

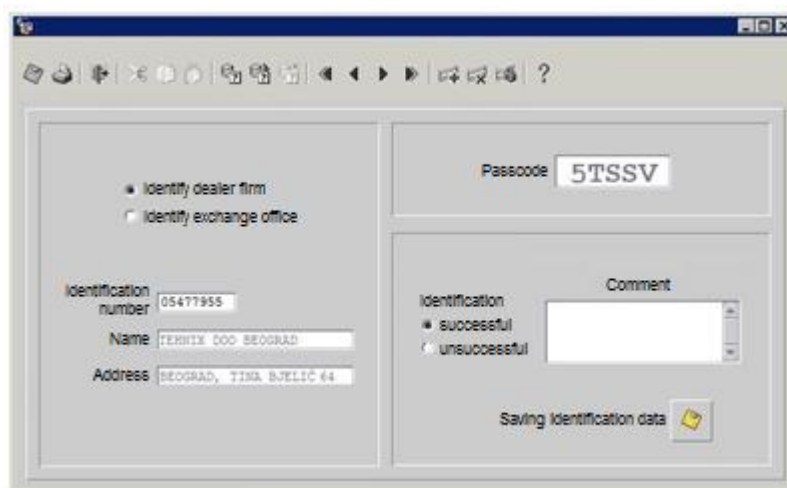
The original software-implemented authentication of authorized external dealers consists of generating a password, i.e. passcode for each external dealer and checking the pascode at the beginning of a telephone conversation between an external dealer and a bank dealer. Passcode is a unique alphanumeric data of a certain length and consists of large letters of the alphabet and digits, excluding the letter 'O' and the digit '0' in order to avoid possible confusion when writing these two signs. The bank automatically generates a bank account for each external dealer and sends it to him at the address he applied to the bank. An external dealer can be a partner company or a currency exchange office. Each company gets its own unique passcode. The exchange office has one or more exchange offices located at different addresses. In agreement with the exchange, it is decided whether the same exchange rate will be assigned to all exchange offices of that exchange office, or a different board will be generated for each exchange point. In a telephone conversation initiated by an external dealer, the bank dealer pays an ex-dealer for his passcode. When an external dealer announces a passcode, a bank dealer in the system on the basis of that passcode recognizes which external dealer is working and tells him the information stored for him. In Figure 5, a screen display for generating a passcode for an external dealer firm is given. In Figure 6, a screen display for generating a passcode for an authorized exchange office is given, in the case where different passcodes are generated for all of its exchange sub offices. On the screen display there is a radio group that defines whether the exchange sub offices will have the same passcode or different passcodes. In Figure 7, a screen display is used to identify an external dealer, whether it is a dealer firm or an authorized exchange.



**Figure 5:** The passcode generating for external dealer firm



**Figure 6:** The passcode generating for exchange sub offices of exchange office



**Figure 7:** Identification a dealer firm or an external authorized exchange office

## 7. CONCLUSION

Efficient data protection is required both for storage on computer systems, as well as for transmission by communication paths. The problem that has arisen either by disrupting information security by unauthorized access to information can cause catastrophic consequences in organizational systems such as, for example, banking, judiciary, military, medical and other systems.

The ISO 27001 standard provides organizations with a framework for securing information security. All types of measures that comply with the ISO 27001 standard, and in particular program measures, can be applied in banks. By selecting the appropriate encryption method and program implementation of the encryption algorithm, the basic measure of protecting "sleeping" data and data transmitted by communication channels is realized. Each cryptographic algorithm has its own advantages and disadvantages. Symmetric algorithms are best suited to solve the required confidentiality because they are faster and look for smaller keys. Symmetric algorithms solve all requirements except intangibility.

Asymmetric algorithms are best suited for solving integrity and authenticity requirements, and they also solve non-compliance requirements. When it comes to confidentiality requirements, asymmetric algorithms are only used to exchange a symmetric key that encrypts the message and ensures its confidentiality. Hashing algorithms are used in integrity protection, and the best way to solve is authorization requests. Some

systems use a combination of these algorithms and thus exploit their stronger sides. Such cryptographic systems are called hybrid systems. Examples of algorithms of these systems are: digital envelope, digital signature, digital stamp and digital certificate.

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## BENCHMARKING AS THE QUALITY MANAGEMENT TOOL FOR THE EXCELLENCE ASSESSMENT OF MEDICINES REGULATORY AUTHORITIES IN EUROPE

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**Abstract:** Nowadays, majority of European Union (EU) member states use international benchmarking as a quality management tool for guiding medicines regulatory policy priorities. Unfortunately, there is limited research on how medicines regulatory authorities use this tool for continual improvement. The concept of Benchmarking of the European Medicines Agencies (BEMA) aims at harmonizing regulatory performance and procedures in each Member State's medicines regulatory authority. Therefore, the paper strives to explore how medicines regulatory authorities in EU perceive the significance of the BEMA methodology itself, thus highlighting its positive and negative aspects. Although some limitations of the BEMA have been identified, the key findings indicate that all the medicines regulatory authorities involved in the BEMA process are confident that the BEMA methodology can be a useful tool for continuous improvement. It should be noted that only the authorities within the EU member states could be the part of BEMA exercise, although it could be potentially used in candidate countries in preparing for the EU membership.

**Keywords:** quality management, quality assessment, benchmarking, medicines regulatory authorities, EU

### 1. INTRODUCTION

Quality improvement in medicines regulatory authorities has required a series of changes that have had a significant impact on medical practice. These changes have led to the creation of such an organizational culture, based on appropriate social and moral principles, in which the medical world, supported by many other disciplines, is trying to find the optimal way to take care of each individual patient (Tosic et al. 2017). In the European Union, a well-established regulatory system ensures that the human and veterinary medicinal products available for patient use are acceptable in every way and this means encompassing various activities that aim to ensure the safety, efficacy and quality of medicines as well as the appropriateness and accuracy of product information (Pejovic et al., 2014). The majority of researchers agree, on a wider scale, that regulatory work in medicines regulatory authorities should be performed with accountability and transparency (Ibid.). The regulatory performance of the medicines regulatory authorities should be regularly and systematically monitored in order to identify problems in the process and to determine if all the implemented activities are in line with the strategic goals of these authorities. Various methodologies can be used to assess the performance of medicines regulatory authorities, such as self-assessment, supervisory authority assessment as well as a review by another medicines regulatory authority dealing with the same activities – peer review. These approaches can all complement each other in assessing the performance of medicines regulatory authorities, but can also help them identify number of areas for continual improvement.

Various tools and/or models like Total Quality Management (TQM), European Foundation for Quality Management, Balanced Score Cards (BSC) and terms like “Best Practices” and “World Class Manufacturing” have prevailed in discussions about quality management in different years. In order to improve operations they first had to be measured and a new target had to be set. For this, a tool called benchmarking was created (Putkiranta, 2012). The benchmarking, defined as the comparison using a set of specific indicators, was, until recently, the domain of market specialists. This changed, however, with the publication by the World Health Organisation (WHO) of its report *Health Systems: Improving Performance* (2000) which thrust international health system comparisons to the forefront of high-level political discussions, highlighting the potential role and pitfalls of such comparisons (Wait and Nolte, 2005). Since then, many countries have used international benchmarking as a basis for guiding medicines regulatory policy priorities.

The concept of Benchmarking of the European Medicines Agencies (BEMA) was first discussed at the Heads of Medicines Agencies (HMA) meeting in Rome in November 2003. It builds on an earlier initiative (such as the Pan European Regulatory Forum (PERF)) whose main role was to help candidate countries for EU membership to fully prepare and adjust their regulatory systems to EU requirements (Pejovic, 2012). The initiative for this methodology was given by the HMA which established a steering group that had exclusive jurisdiction to coordinate the implementation of the BEMA methodology and analyze the results (HMA, 2006). A steering group was established in January 2004 to develop proposals for the exercise, including a series of

key performance indicators as well as methodology of how to identify and share the best practices (HMA, 2012). To the best of the authors' knowledge, there is no paper that deals with such subjects generally. According to the Heads of Medicines Agencies (2018), the aim of the BEMA methodology is "to contribute to the development of a world-class regulatory system for medicinal products based on a network of authorities operating to best practice standards". The main purpose of BEMA is to gather the information on best regulatory practice thus enabling identification of areas for continual improvement within authorities. It is also significant to point out that BEMA is not designed for direct comparison of, or ranking of, medicines authorities. Medicines authorities are encouraged to develop suitable best practices in order to enable an improved operation of the network of medicines authorities. The entire process of anonymization has been agreed so that none of the information held in the centralized database is attributable to any authority. Therefore, HMA (2016) claims that the most valuable part of the BEMA is that it is a form of self-assessment enhanced by consultancy carried out by authorities that are also fulfilling national responsibilities under EU legislation.

In this paper, after the introduction, the review begins with the brief description of the BEMA methodology and the BEMA questionnaire. The next section of the review is dedicated to the research methodology. The results follow. Additionally, the paper presents key findings thus presenting all areas of strengths and weaknesses, as well as all the positive and negative aspects of the BEMA. These findings provide an indication of the status of the medicines regulatory authorities with respect to their willingness for continuous improvement within BEMA in any area where improvement might be made. Finally, the review offers some conclusion remarks.

## **2. BENCHMARKING OF THE EUROPEAN MEDICINES AGENCIES (BEMA)**

During time, the benchmarking has evolved into a well-established methodology for comparing individual management systems and it is not just an inspection or an audit designed to identify non-compliance. It is a business practice which stimulates process improvement by determining best practices across organizations through performance measurement and understanding those factors which enabled the higher performance of the organizations (Watson, 1994). Actually, the essence of benchmarking lies in the fact that it is "the process of identifying the highest standards of excellence" (Milosevic et al., 2013). In the following chapter, we will discuss the implementation of this popular methodology within medicines regulatory authorities in EU.

### **2.1 BEMA Methodology**

In order to identify the best practice and improve their system, medicines regulatory authorities apply BEMA methodology. The BEMA is a quality management tool for continuous regulatory and public service performance improvement. It is based on comparing and finding best practices, sharing positive experiences, ad hoc consultations from colleagues coming from a similar work environment and/or working on similar jobs (Pejovic et al. 2014). Therefore, the BEMA methodology does not serve for the competition or self-promotion of medicines authorities but solely for the purpose of assisting the internal improvement of the whole process. This is the basic concept of the BEMA methodology, but in its background is the tendency of the HMA to monitor the work of all the medicines regulatory authorities in the EU by standardizing their work and raising their performance to the highest possible level (Ibid.). The BEMA methodology includes both self-assessment and peer-review assessment and is broadly based on ISO 9004 guidelines. "Self-assessment against a performance excellence model by organizations within a multi-organizational network can provide an effective basis for cooperative learning and benchmarking" (Saunders and Mann, 2005). On the other hand, according to ISO 17000:2004, peer-assessment is "assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group". The peer review assessment is important as it allows each medicines regulatory authority to be visited by teams of specially trained assessors for an independent assessment against the performance indicators. The usage of ISO standards in the BEMA methodology ensures mutual understanding between different parties in the process in order to develop a world-class pharmaceutical regulatory system based on the mutual cooperation of best practice standards. Using the ISO 9004, a reference questionnaire was defined, which initially included only the areas of pharmacovigilance and documentation assessment activities which were later added to parts related to the general organization and the connection with the inspection bodies. From September 2012 to October 2014, the total of 47 benchmarking visits to medicines regulatory authorities or ministries responsible for the field of medicines were made, of which 17 agencies regulate both human and veterinary medicines, 14 regulate human medicines only and 14 regulate veterinary medicines only (HMA, 2016). Forty two assessors from 18 countries and 24 authorities participated in these visits, with three assessors from different authorities in each team (Ibid.). First three BEMA cycles showed some weaknesses, which were reflected in the inadequate training of BEMA assessors, unequal evaluation criteria etc. Therefore, the steering group within the European Medicines Agency (EMA), "the key central body for European regulatory decision-making activities" (Pejovic et al. 2011). has launched an action to define a new version of this questionnaire, which has been significantly improved as well as a series of very serious BEMA assessors

trainings (twice a year), removing deficiencies observed in previous visits. Therefore, this enhanced version is often referred to as the BEMA IV methodology and, according to this version, medicines regulatory authorities are currently being evaluated. The key findings of these visits were entered into an anonymized database which is not designed for direct comparison of, or ranking of, medical regulatory authorities, but will be used for analysis and as a useful source of good practices for the benefit of the network of authorities, continuous improvement within the BEMA methodology or at any stage when the network of authorities is considering improvements. The description of each BEMA cycle from January 2004 to September 2018 is presented in the Table 1.

**Table 1: BEMA Assessments (Heads of Medicines Agencies, 2018)**

<b>BEMA I</b>	<b>BEMA II</b>
Began in January 2004 with the establishment of the steering group and the development of the KPIs, questionnaire and methodology. Visits to agencies took place between June 2005 and May 2006 and successfully established the methodology as a tool for benchmarking of the network of agencies in the EU/EEA.	Development of the second cycle was based on formal feedback gathered from agencies and assessors at the end of the first cycle and the experiences of the steering group and logistics team, in order to make amendments, including the KPIs for the revised questionnaire. Visits took place between June 2008 and July 2011.
<b>BEMA III</b>	<b>BEMA IV</b>
The HMA Strategy 2011-2015 was used to direct an extensive review of the KPIs resulting in a more streamlined and focused questionnaire. Formal feedback gathered from agencies and assessors at the end of the second cycle, and the experiences of the steering group and logistics team, were used to make amendments to programme. The BEMA III began in September 2012 with 47 agencies to be visited by October 2014.	It was established following a positive outcome of the previous BEMA cycles, allowing its development into a tool for the improvement of quality management system and consistency of best practices across the EU network of medicines agencies. Revision of the KPIs and updates in line with the EU Medicines Agencies Network Strategy to 2020 resulted in development of comprehensive, yet focused questionnaire. BEMA IV began in June 2016 with 47 agencies to be visited by October 2018.

## 2.2. BEMA Questionnaire

In order to achieve quality and excellence, every organization should review its performance in relation to the specified criteria, determine the current levels of maturity and determine its strengths and weaknesses (Horvat, 2018). Criteria given for a higher level of maturity can help the organization understand the issues to consider and help it determine the necessary improvements to achieve a higher level of maturity (ISO 9004:2009). Hence, the new rating system was introduced based on the concept of Capability Maturity Model (Table 2) in which a rating scale (5 levels) is complemented by a statement of maturity for each rating level, specific for each indicator (HMA, 2016). According to the rating system presented below, each question from the questionnaire is evaluated and the final assessment for the given question is obtained by the consensus of all team members. If the team decides so, it is possible to make estimates that correspond to the half of one score (0.5). Based on the experience, it has been decided not to give a final rating to an authority, but to evaluate each individual segment defined by the questionnaire. The BEMA evaluation ends with an exchange of experiences between the two sides and with the comparison of the obtained grades during BEMA visit with the grades achieved after the self-assessment phase. If there is a significant deviation in the rating, this is an exceptional opportunity to discuss it with team members. Also, "the best in class" grade is never given, because it would mean that further improvement of the process is not necessary, which in practice is never the case. Contrary to the implementation of the BEMA I, the tendency of the evaluators, during the visits to the authorities is often focused on interviews and on concrete evidence, rather than on the presentation of the results contained in the self-assessment questionnaire itself (Ibid.).

**Table 2: Capability Maturity Model: The Rating System Applied in the BEMA Procedure**

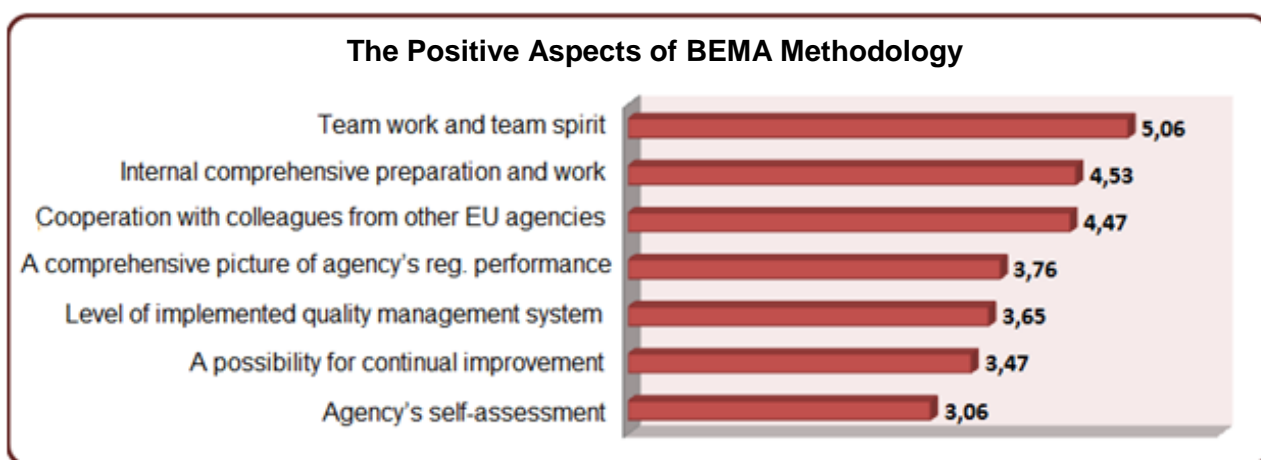
<b>Maturity</b>	<b>Performance Level</b>	<b>Note</b>
1	There is no formal approach	No systematic approach, no matching results, poor or unpredictable results
2	Reactive approach	Approach based on problem solving or the implementation of certain corrections, a minimum number of data is available
3	A stable, formal system approach	Systematic approach based on processes, the initial phase in stematic improvement; there are data on compliance with set goals and the existence of an improvement trend
4	Continuous improvement is emphasized	The improvement process, good results and a constant improvement trend are used
5	Performance "best-in-class"	The improvement process is fully integrated; benchmarking results matching "best-in-class" performance are displayed



#### 4. RESULTS

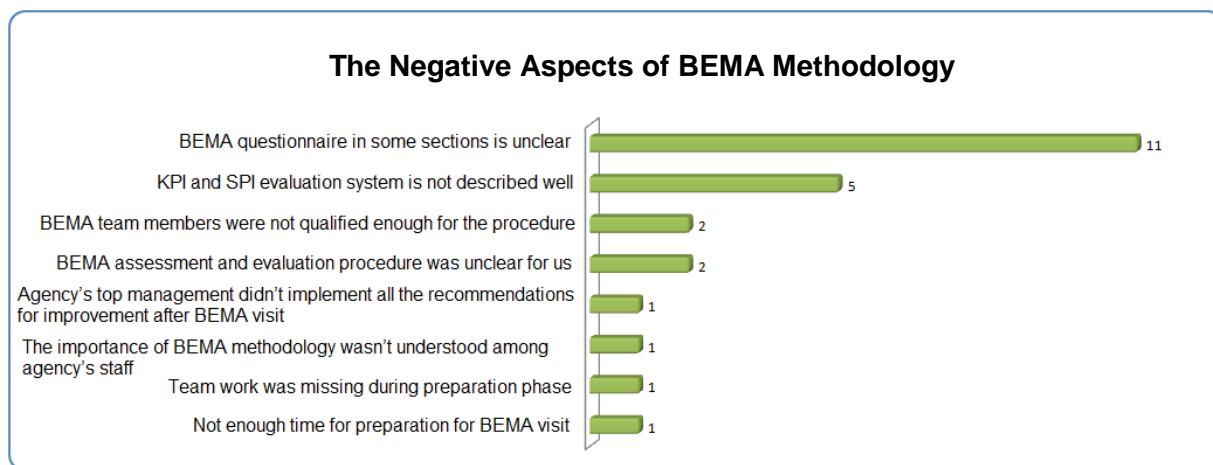
Finally, a total of 17 replies were received, which makes 43.59% of the total number of questionnaires sent. Respondent regulatory authorities have within their jurisdiction human, veterinary medicines, medical devices, but also a number of specific areas, such as cosmetics, tattoo products, precursors, price fixing and medication consumption monitoring, etc. Regarding the size of the authorities that responded to the questionnaire, the highest number is those with more than 200 employees, which indicates good potential for adequate performance of all regulatory functions when human resources are in question. The majority of medicines regulatory authorities have a well-established and certified quality management system, while in a few authorities the quality management system is not formalized, or is being implemented.

By analyzing the responses, all medicines regulatory authorities involved in the BEMA process believe that the BEMA methodology is a useful tool for continuous improvement of performance and they support its further organization by the HMA. Furthermore, it was possible for respondents to evaluate certain positive aspects of the BEMA methodology, as well as to indicate those negative. Seven positive aspects of the mentioned methodology were evaluated, where it was necessary to rank on the scale of 1 (the most useful aspect) to 7 (least useful aspect). Figure 1 shows a summary of this assessment, ie. the mean value of the assessments given by the respondents for each aspect of the BEMA.



**Figure 1:** Mean Values of the Assessments of the Positive Aspects of the BEMA

The results have shown that the respondents, as the most important and beneficial aspects of the BEMA methodology, highlighted the need to carry out self-assessment in the preparatory phase (grade 3.06), giving it the possibility for continual improvement (grade 3.47), as well as the ability to assess level of the implemented quality management system (grade 3.65). Relatively high rating (3.76) respondents gave an aspect "it is an opportunity to get a comprehensive picture of agency's regulatory performance, as whole". On the other hand, low ratings indicate the aspect of cooperation with colleagues from other European agencies (grade 4.47), who are actually members of the BEMA assessment team, which is also indicated by the individual comments of the respondents that there is not enough education for the members of the BEMA team, or that their criteria for assessing the regulatory functions of the medicines regulatory authorities are uneven. However, the results in this part of the questionnaire also point to the fact that there are obvious problems with the internal organization and preparation for the BEMA methodology (grade 4.53), which must be comprehensive, long-lasting and involve multidisciplinary teams, because the aspect of teamwork is marked the lowest ratings (5.06). It can be concluded that, with the development of the regulatory performance level, the importance and role of the BEMA methodology are changed, so that it is not viewed only as an additional obligation, but also as a possibility for continuous improvement of performance as well as a quality management tool that medicines regulatory authorities should introduce into their everyday work.



**Figure 2:** Mean Values of the Assessments of the Negative Aspects of the BEMA

Regarding the negative aspects of the BEMA methodology (Figure 2), the dominant number of responses concerned the fact that the BEMA questionnaire, which is the basis for the implementation of the BEMA methodology, is, in some areas, unclear. This is actually an essential problem for the implementation of the entire procedure, because, according to the questionnaire, self-evaluation of the medicines regulatory authorities is carried out at the preparatory stage followed by the actual assessment by the BEMA team. If there is a fundamental lack of understanding of the questionnaire, this can lead to poor results of assessing and representing the regulatory performance of a given authority worse than it actually is. The second prominent problem, which is directly related to the questionnaire, is the system of evaluating key and specific performance indicators, which causes a suspicion in the investigated medicines regulatory authority, and a doubt about the correctness of the assessment.

## 5. CONCLUSION

The BEMA methodology is an excellent way of sharing best practices in the work of regulatory authorities across Europe, helping the medicines regulatory authorities with less developed capabilities to find the most appropriate way to organize their regulatory functions. The primary goal of organizing and implementing this methodology within EU is to create such a quality regulatory environment in which any regulatory body will be able to accept and recognize the work of other authorities. This will significantly save resources and ultimately create preconditions for creating a single market for medicines in Europe, thus creating the unique capacity of all medicines authorities to implement adequate health protection. All surveyed medicines regulatory authorities support the further organization of the BEMA because they consider it to be a unique opportunity to compare regulatory functions between them. General conclusion indicates that medicines regulatory authorities in Europe accept BEMA methodology as a quality management tool for improving regulatory functions, but do not perceive its' all aspects. Some limitations of the BEMA have been identified, which directly influence the acceptance of the BEMA questionnaire in the regular processes of measuring and improving the performance, which is its main goal. As it is already emphasized, there are no similar data available in the scientific literature on examining the role of the medicines regulatory authorities in quality infrastructure, their consideration of the significance of the quality management system, as well as data on the possible application of the benchmarking methodology for the continual improvement of regulatory functions. The role of medicines regulatory authorities in public health system in every country is undeniable, as they are responsible for assuring quality, safe and efficacious medicines and medical devices. Therefore, the measure of their quality performance impacts the general population, in terms of medicines access and availability. The significance of the conducted survey is that it provides the basis for further research of the new ways for the quality management system improvement within the medicines regulatory authorities in Europe. Such research would be unique, having in mind the fact that there are no similar published results.

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# QUALITY OF LIFE AND DIGITAL TRANSFORMATION IN HEALTHCARE

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**Abstract:** *Paper explores the perception of the quality of life and its relations with the overall health of the population and the healthcare system. New technological improvements have led to a transformation in business, hence the healthcare system as well. Paper presents the main trends in the field of healthcare digitalization process and illuminates the problems which can occur, such as safety of privileged patient information, use of different applications, managing and storage of patient data etc. As well as selecting benefits of digitalization process and it impacts on quality of life.*

**Keywords:** *quality of life, quality in healthcare, digital transformation, healthcare industry*

## 1. INTRODUCTION

The quality of life is not simple to define, for it involves several aspects of individual satisfaction in different spheres of life, as well as the psycho-physical condition of a person. However, this term is used more and more today and it is considered that the way citizens grade the quality of life will replace the accepted GDP analytics. It should also be noted that the well-being of citizens is most commonly related to the term of quality of life. And so, to begin, we will consider the definitions of the quality of life, health status, as well as health-related quality of life.

The quality of life can be also defined as an overall well-being comprising objective descriptors and subjective evaluations of physical, social, material and emotional well-being along with the level of personal development and purposeful activity weighted by a personal set of values (Felce and Perry, 1993). It can also be formulated in terms of one's context (standard of living), absence of well-being (depression), or in a collective manner (Pollard and Lee, 2003). As written in the report "Wellbeing and policy", countries worldwide are becoming attracted to these appealing ideas but are worried about how they can be implemented in real life. The authors of the report are of the opinion that such ideas could encourage the governments and individuals to make 'better' decisions that would contribute to enhancing the overall wellbeing.

Chancellor Merkel pointed to the relevance of the notion of wellbeing by stressing the following: Industrialized countries do not only have the GDP and growth issues. Even hard-nosed central bankers, like Ben Bernanke, have argued: "The ultimate purpose of economics, of course, is to understand and promote the enhancement of well-being." Very few academics would argue that a country should invest efforts into maximizing the GDP (O'Donnell et al., 2014).

Besides that, the digitalization of the process leads to completely new relations in doing business. And when we discuss the healthcare system, the data relating to the well-being of citizens has become more valuable on the grey market than credit card information. This paper deals with the perception of the quality of life and its relationship with the health status of the individual, as well as the way in which the digitalization of the healthcare industry affects the quality of life; but also, how one measures quality within the healthcare system.

## 2. QUALITY OF LIFE, HEALTH-RELATED QUALITY OF LIFE AND HEALTH STATUS-WHAT IS THE DIFFERENCE?

World Health Organization (WHO) provide a highly influential definition of health, they defines health as "a state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity" (WHO, 2014). WHO definition include some key aspects like social well-being and the emphasis on more than the absence of disease. That is important because not everyone agrees on the inclusion of social well-being in the definition of health (Torrance,1987). For example, some authors define health as "an individual's level of function" (Patrick et al.,1982), where "optimum function" is judged in comparison to "society's standards of physical and mental well-being".

Defining QoL, Quality of life has proven challenging (Brazier et al., 2014), (Moons, 2006) and many approaches to defining quality of life exist (Ferrans, 1990). There are approaches based on subjective well-being, expectations and human needs (Bowling, 2005).



A related literature on well-being distinguishes between approaches based on objective lists, preference satisfaction, hedonism, flourishing, and life satisfaction (Peasgood et al, 2014).

Other examples of definitions of Quality of life are: "an individual's" perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (Kuyken and Group, 1995) , "a conscious cognitive judgment of satisfaction with one's life" (Rejeski and Mihalko, 2001).

Defining HRQoL, Health-related quality of life has also been problematic (Bowling et al.,1995) and in the literature we can identified a few definitions of HRQoL. For example, HRQoL can be defined as "how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health" (Hays, 2008), other definition relates HRQoL directly to QoL: "quality of life is an all inclusive concept incorporating all factors that impact upon an individual's life. Health-related quality of life includes only those factors that are part of an individual's health" (Torrance, 1987). According to Torrance non-health aspects of QoL, like economic and political circumstances, are not included in HRQoL.

### **3. QUALITY IN HEALTHCARE**

Numerous reasons testify why it is important to improve quality of healthcare, including enhancing the accountability of health practitioners and managers, resource efficiency, minimizing and identifying medical errors while maximizing the use of effective care and improving outcomes, and aligning care to what patients want in addition to what they need (Subhash, 2003).

When it comes to quality assessment, there is only but a handful of frameworks used for analytic purposes. These frameworks have guided the measure development initiatives in both the private and public sectors, and the most influential among them was implemented by the Institute of Medicine (IOM). The framework itself examines six criteria throughout the healthcare system (Institute of Medicine, 2001): Safety; Effectiveness; Patient-centeredness; Timeliness; Efficiency; Equitability.

The measures used currently give priority to some of these criteria more than to others. For example, the present majority of measures is focused on safety and effectiveness, whereas only a small portion gives importance to timeliness and patient-centeredness. And even fewer measures assess the importance of efficiency and equitability (Institute of Medicine, 2005).

Frameworks like the ones implemented by IOM domains also prove to be a good learning curve for helping others understand the true meaning and importance of quality measures. And research has proven that by having a framework with which you can grasp the relevance of quality measures, you in fact are capable of valuing a wider range of quality indicators. So, if you were to offer a detailed explanation about the importance of safety, efficiency and patient-centeredness, consumers would have no trouble grasping the relevance of all three criteria. Better yet, when you take those three IOM domains and present them in user-friendly versions of the measures they represent, consumer are able to comprehend the importance of those measures more clearly and from a personal healthcare perspective (Hibbard and Pawlson 2004).

It is important to mention that the rising cost of health care have led to situation that healthcare industry has become especially oriented on improving outcomes and patient satisfaction (Sarkissian, 2017). We can compare it with definition of quality system "a set of interrelated or interacting elements which is using a variety of resources to achieve objectives related to quality" which are focused on fulfilling and overcoming user's requirements (Filipović and Đurić, 2010). According to the National Association for Healthcare Quality (NAHQ) we can found a set of main functions which are recognized to advance the profession and ensure that health care quality leaders are sufficiently prepared: Patient Safety; Regulatory and Accreditation; Quality Review and Accountability; Performance and Process Improvement; Health Data Analytics; Population Health and Care Transitions (Curdy et al., 2017).

Setting quality as top priority of organization it can result in achievement changes in goals, guidelines, attitudes, and activities.

### **4. DIGITALIZATION AND DIGITAL TRANSFORMATION IH HEALTHCARE**

When it comes to the comprehension of the influences and alterations on the business side of things, as it is written in I-scoop text, it's important that we research digitization, digitalization and digital transformation right form the beginning.

When it comes to aspect of digitization, there are two closely-related meanings that we can consider crucial:

Digitization presents the transformation of analog/physical things (paperwork, photographs, sounds etc.) and creation of their digital counterparts (bits and bytes). Digitized information is not limited to a specific set of materials, in the final instance, it is grounded in the configurations of materials. Relying on that fact we can

see how digitization mediates between the material and the immaterial (Manoff, 2006) which makes digitization a united process (Hayles, 2003).

Digitized information is the only one that can be represented on any set of transistors, “all forms of data such as alphanumeric text, graphics, still and moving pictures, and sounds” can be digitized (Verhulst, 2002). “All signals are chopped into little pieces” (Van Dijk, 2005) and encoded as strings of 1s and 0s, and that is the fundamental process. It is also important that this process can be applied to almost every information, occurs through specific technical mechanisms and requires specific technical infrastructures that modify the original signal itself.

On the other hand, digitalization serves to: Create revenue; Improve business; Replace/transform business processes (instead of digitizing them); Create the foundation for digital business processes;

The structure of this endeavor uses digital information as the core, whereas digital technologies and data (digitized and natively digital) are used as the building material.

If digitalization is also about changing business operations, business models and even revenue streams and new business opportunities, then what is the difference between digital transformation and digitalization?

It all comes down to the range and scope of it all. In comparison to digitalization, digital transformation is a much broader concept of upgrading to digital business. The foundation you build with a digital transformation strategy is much bigger because it requires more elements to help it function. Digital transformation originally served a very simplistic purpose of converting paper into digital information – since that time, it has significantly evolved.

Nextgov reports that: “Around three-quarters of the \$80 billion the federal government spends on information technology each year is used just to keep legacy systems running.” Even though technology is considered a crucial element in terms of digital transformation, this goes to demonstrate that rather than invest into new tech, it is often more about ridding ourselves of outdated process and legacy technology (Moore, 2015). According to a study done by Triger Text (and using research conducted by HIMSS Analytics): “Despite widespread use of smartphones and other mobile devices among healthcare providers, 90% of hospitals still use pagers and overpay by 45% to maintain legacy paging services.” (Landi, 2016).

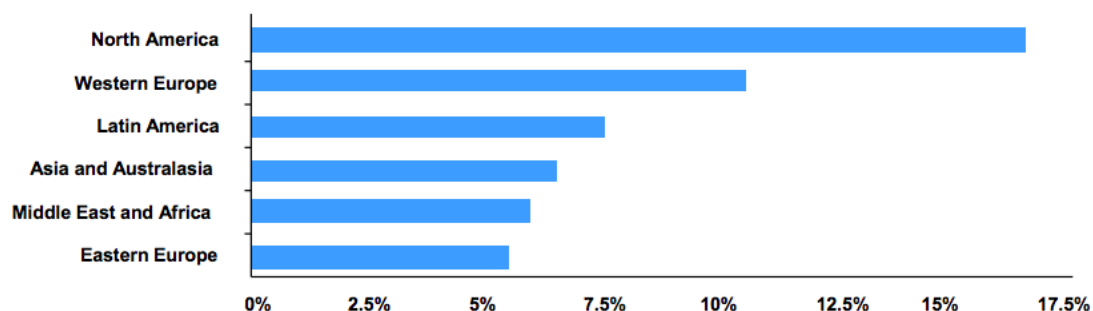
And these types of examples are present in all industries, where the prevalence of legacy technology stand in the way of a revolutionary digital transformation strategy that can only contribute to a business (Mark Samuels, 2015).

#### 4.1. Digital Transformation In Healthcare Industry

Smart care, care anywhere, empowered care and intelligent healthcare enterprise – these are the four digital themes that will prove to be essential to the digital transformation of healthcare in the future.

- 1) Smart Care will use precision medicine, robotics and medical printing to improve patient outcomes and lower healthcare costs.
- 2) Care Anywhere will make household healthcare a reality, with the help of advances in connected homes and virtual care.
- 3) Empowered Care will give citizens more control in managing their well-being and healthcare through the development of “living services”.
- 4) Intelligent Health Enterprises makes possible for healthcare workers and their enterprises the option of monitoring patient health more effectively in real time, with the help of data-driven solutions.

Value-based healthcare is quickly becoming reality with the advancement of the digital aspect. With new technological advancements, the gap between the physical and digital world is becoming much smaller. As a result, hospitals and other healthcare facilities are now available to consumers with a simple click, scroll or tap. You now have combined smart sensors, devices and highly connected software that can lead patients to exactly what they need – low-cost healthcare outcomes with top-quality experience and convenience (World Economic Forum, 2016).



Source: The Economist Intelligence Unit

Figure1. Digital Transformation of Industries Healthcare Industry, (World Economic Forum, 2016)

Nearly 18% (\$3.2 trillion) of the total GDP of the United States was accounted to national health expenditures in 2015. Additional research found that as much as \$300 billion can be saved in the healthcare sector with the help of the digital revolution. This alone should paint a picture of how influential the introduction of new technologies could be when it comes to the healthcare market. In fact, CISCO research goes to define several more influential ways this can happen:

#### Telemedicine

Back in 2015, a majority of doctors and physicians were surveyed to answer whether telemedicine is a better way of managing chronic diseases or not. More than 80% of those surveyed answered that it was a more efficient method than a traditional visit to the office (AHA, 2015). The fact is that with telemedicine, both doctors and patients gain more freedom and accessibility. For one, patients would no longer be limited in terms of geographical location and distance from their physicians. This means that even patients in the most remote of areas would be eligible to receive the highest level of care afforded to those living downtown. And all it would take is a good Internet connection and a smartphone. This in itself ends up saving patients both time and money. Instead of wasting hours waiting and travelling for a simple check-up or prescriptions, they could receive it within minutes on a conference call.

#### Mobility and Cloud Access

It's estimated that over 65% of interactions with healthcare facilities will occur via mobile devices by the end of this year. In fact, the number of physicians using smartphones and medical apps already exceeds 80%, most of which access drug information on the mobile devices daily. You can wave farewell to the days of extensive paperwork and file rooms, given that all medical facilities and insurance companies are now storing patient records on the cloud, giving you 24/7 access to your test results, bloodwork etc.

#### Wearables and IoT

With the constant progress of technology come many perks, even in medicinal terms. ECGs, DIY blood screening, thermometers and other types of tests can now be conducted in the comfort of your home with mobile devices the size of car keys. With the introduction of automation, patients are even able to keep track of their weight, pulse, oxygen levels etc. all of which they can then post online for their physician to inspect. And as a result, people are able to prevent and avoid risks of heart disease and other chronic illnesses, which can ultimately save their lives (PWC, 2018).

#### Artificial Intelligence and Big Data

Big data holds the true power of the digital world, and the same goes for healthcare. Most people consider big data as a great feedback and review tool. However, it holds a much greater potential for identifying health-related risk factors and preventing them with pre-emptive treatment. Even more exciting: with the rise of the Internet of (Medical) Things (IoMT), mobile and wearable devices are increasingly connected, working together to create a cohesive medical report accessible anywhere by your healthcare provider. And this type of data goes beyond the individual patient – it holds the key of studying entire cultures and countries to help predict mass healthcare trends (Newman, 2017).

#### Empowered Consumers

Everything we mentioned up until now has led to the creation of a completely new and game-changing trend in the world of healthcare – empowered patients. We as patients are finally in a position where we get to dictate it all. No more long waits and unplanned overcharges associated with healthcare – we now have equal access to all forms of healthcare, which leads to higher overall satisfaction rates (Sherman, 2015).

## 4.2. Quality in e-Health

It looks really clear that e-health includes more than just technological development. The Internet created new opportunities and challenges to the traditional health care information technology industry, the use of a new term to address these issues seemed appropriate. According to Eysenbach, e-health can be defined as an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology (Eysenbach, 2001).

In terms of medicine, ICT (Information and Communication Technologies) development can lead to better quality of healthcare. A typical example here would be the application of high-tech sensors (i.e. pulse, body

temperature, ECG, etc.), able to provide real-time data via wired or wireless communications technologies, interactive interface etc. This improvement actually presents “e-Health” – which is the primary engine for assisting patients. It does this by combining the use of electronic communication and information technology with the use of digital data transmitted, stored and retrieved electronically, both locally and at distance.

You are now capable to constantly monitor and record the condition of patients with chronic diseases, which you can then log within a larger database. The data that is gathered from these sensory devices is usually analyzed, monitored and managed by medical professionals. And the main advantage of such applications is that they trump time and space. They can capture any atypical symptoms or bodily activity at any time and in any place, so you are no longer limited geographically. Which means that patients can be monitored at their natural environment (Varshney, 2007).

The only re-occurring issue here is the complexity when it comes to managing this type of data. There are times when medical specialists are confronted with inaccurate, incomplete or overwhelming amounts of input. This, in term, leads to questions concerning the quality, security and privacy of the data in this domain. The fact remains that the quality of the data gathered in the healthcare domain always was and should be the priority. Otherwise, we risk achieving a negative effect of the applications used to collect all the information necessary. And if we choose to ignore the data collected, it also impacts the decision-making process.

In the last couple of years, technological improvements have been opening new possibilities in healthcare and the practice of medicine. But those possibilities also carry inherit risks and leave decision-makers with numerous unanswered questions regarding: quality, security, privacy, ethics and risk management and other important matters.

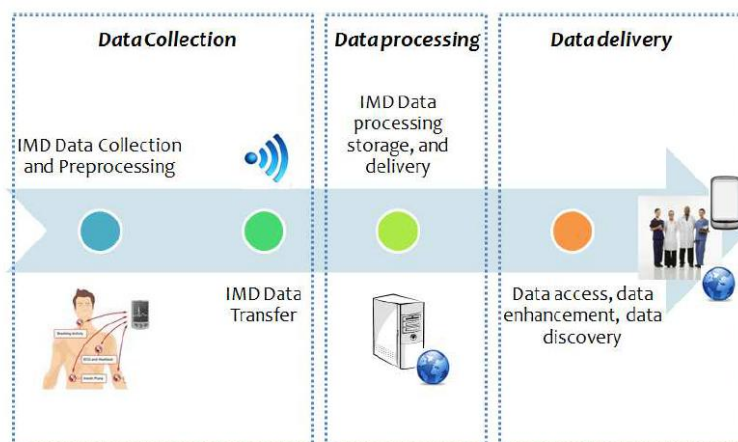
Some surveys and approaches have showed the importance of data quality for end-users, in particular, in healthcare domain (Shaw et al. 2009).

Many quality criteria have been proposed without a general consensus; in fact, each domain has its specific vision of data quality as well as the solutions to solve the quality problems (Wang and Strong, 1996). Data quality

is often considered as “fitness-for-use”. It is based on the specific use of data and the requirements to be satisfied. To tackle this issue, based on existing quality modeling approaches (Wang and Strong, 1996), (Naumann and Rolker 2000), (AHIMA, 1998), we can analyze the e-health monitoring systems according to appropriate quality criteria. Such strategy aims to manage data quality at every point, which should lead to the minimization of potentially poor data quality from spreading.

#### 4.2.1 Impacting data quality

To correctly identify data quality issues, we have firstly to identify the source of the quality problems, analyze its impact and, where possible, propose a solution. Some difficulties are related to technology (i.e. equipment, QoS (Quality of Service), to human intervention (input errors, misunderstanding...), or to process of data transformation (i.e. optimal analysis and processing). According to Gutiérrez and Riveill (2011) there are three main levels of data management and processing over the system defined as: Data collection (sensor data collection, pre-processing and transfer), Data processing (data processing, storage and delivery) and Data discovery (data access, enhancement and discovery).



**Figure2.** Data quality analysis for e-health monitoring applications, (2010).

## 5. INFORMATION SECURITY MANAGEMENT (ISM)

Just like any other knowledge intensive and information-based enterprise, the healthcare industry depends on the IT sector to analyze, acquire, manage and disseminate all information and expertise related to healthcare (William and Herbert, 2009). IT solutions are used to: Develop the decision-making process; Promote information exchange; Aid in self-care and professional support; Improve the effectiveness of healthcare facilities; Make electronic records of patient information (Economic Commission for Africa, 1999).

Information that relates directly to the health of a patients in defined as personal health information. This type of information includes everything – from a person’s health condition and use of health services to any potential disability or other relevant information (Office of the privacy commissioner, 2001). The way to gain access to such information is through health information systems (HIS). As an integral part of any healthcare system, HIS lays the foundation for processing, analysis and reporting of healthcare information. In additions to this, it also supports the development of the top healthcare indicators needed to monitor and evaluate the overall performance of a particular healthcare system (Matshidze and Hanmer, 2007). In comparison with paper-based data collection, and on the negative side of things, HIS-based collection and data storage can cause certain complications in terms of information protection measures and security (Quynh, 2005).

Information security management (ISM) has a primary goal to ensure business continuity while it reduces the business damage. It can do so with prevention and/or minimization of any security incident impact (Krause and Tipton, 2003). The goal of ISM is to establish, implement, operate, monitor, analyze, revise, maintain and boost information security.

The ISO/IEC 27001 (ISO 27001, 2005) is an internationally recognized standard that provides a specification for ISM systems. One of the standards that supports the implementation of ISO/IEC 27001 is the ISO/IEC 27002 - Code of practice for ISM (ISO 27002, 2005). This standard provides implementation guidance in support of the security controls specified in its clauses and is cross-referenced for this purpose in the ISO/IEC 27001 (ISO 27001, 2005). In 2008, a new standard was published for ISM in healthcare. The ISO/IEC 27799 international standard provides guidance on how best to protect the confidentiality, integrity and availability of their information with the implementation of ISO/IEC 27002 standard (ISO 27799, 2008).

## 6. CONCLUSION

Since the introduction of electronic medical devices (EMRs) back in 2009, the healthcare industry has undergone a major transformation. Providers, payers, and other medical organizations have undertaken the long-term project of securing every patient medical record electronically in order to comply with government regulations. The rewards for current players and new entrants are likely to be quite substantial for creating transformational digital services as scale, considering that the overall amount of finances spent on healthcare annually amounts to \$7.5 trillion. Digitization is still defined as complex and challenging, mostly due to the effect it has on every piece of data, relationship and business interaction. Just consider this – healthcare providers are now able to use apps to track patients and assets, and thus support the experience of the consumer with wayfinding, mapping and scheduling. The potential that such a system carries is endless in terms of: Handling big data; Mass records analysis and comprehension; Creating a top-quality healthcare system. With all this in play, the old data gathered from centers and CRM systems can now be combined with the data collected from digital sources (mobile networks, social media, medical apps, equipment sensors etc.).

As it mentioned, HRQoL means “how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health”, not surprising the fact that governments invest such a big money in improvement of healthcare system in order to achieve better conditions for their citizens aligned with new technologies. As is told at the beginning of the paper, new measure for GDP will be a QoL score, witch is directly connected to healthcare system.

Regarding to that fact healthcare records are among the most hacked data in the world. It is estimated that medical information is worth 10 to 20 times more on the black market than credit card data because of its potential for fraud, identity theft, and abuse (Humer and Finkle, 2014). With the development of technology comes the growth of potential threats and risks as well. So, as the Internet of Things grows, the security of medical devices is beginning to be questioned more and more.

In Nederland’s National Institute for Public Health and the Environment report it is also mentioned that nowadays digitalization in health care is equal to common good. Health data are measured, stored and exchanged in bits and bytes. Digitalizing health data can bring benefits as well as challenges for patient safety. Accordingly it is important that health care providers are aware of the risks related to hackers, viruses, and the safe transfer of data.

A set of different benefits might be achieved by digitalizing health data, and some of the are dedicated to next goals: Improving public health by electronic health data which can be used by health care professionals.

This can be done by combining databases with medical information or using electronic medical data to identify intervention or surveillance strategies. (Lin and Schneeweiss 2016). Securing the privacy of the individual patient is the main challenge in using electronic health care data to improve public health.

Empowering the patients in direct online insight and use of digitalized health data. Direct access of health care services improves patient self-management and safety, but will also affect the workload of health care professionals. In these way communication technologies change the interaction between patient and health care professional (Mold and Lusignan 2015);

Cost reduction can be achieved through implementation of the medical data in electronic health records. (Shen et al. 2015).

As mentioned above, when we discussed the healthcare system, all the digital transformations that are occurring today have a goal to satisfy the demands of the users. By meeting those demands, the level of the quality of life also grows. However, this also brings new issues related to the quality of services, security measures etc. Digital transformations definitely introduce a new era to our way of life and conducting business, and this is what we set out to demonstrate with this paper, as well as to predict new movements and trends. Those who manage to get behind these trends first and meet user demands the most will also gain the largest advantage.

The next step in the continuation of this research can be the analysis of the healthcare system in the Republic of Serbia, as well as grading the quality of life of its citizens.

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## PUBLIC ADMINISTRATION QUALITY DETERMINED BY CUSTOMER-RELATED CAF MODEL

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**Abstract:** CAF model, developed to support the introduction of the idea and the principles of total quality management (TQM) in the public sector, has today become an important tool for measuring quality improvement in public administration. On the other hand, any quality improvement should be directed according to customer satisfaction. Thus, the CAF model is used in this study to evaluate and compare public administration quality including customer-related results, as part of the CAF model. Furthermore, CAF results are compared with the municipalities' quality system maturity level assured by ISO 9001 certificate. The results show significant correlation between CAF scores and maturity level as well as between citizens/customers results and overall CAF scores.

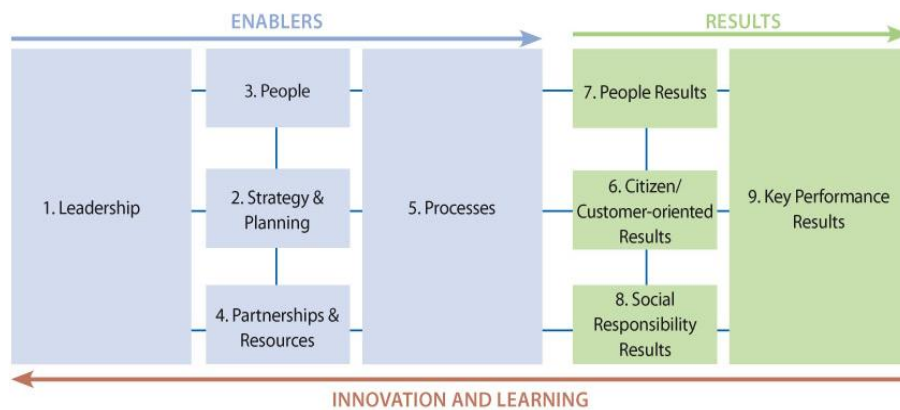
**Keywords:** service quality, public administration, customer satisfaction, municipality, CAF model

### 1. INTRODUCTION

The public administration function is a crucial element of any country, and has many times been a starting point for economic growth and social justice. The need for improvement of performance and results in the area of public services has never been more important (Vakalopoulou et al., 2012). In accordance with the quality management movement, customer focus has become a key issue, with the satisfaction of customer needs and expectations being a major concern (Flynn, 1997; Nwankwo, 1995). According to Schainker (2013), to achieve exceptional service, an organisation must first listen to its customers. In line with this, Hill (et al., 1999) recommend that in order to identify things that are important to customers and to measure the degree by which they are satisfied, it is useful to make an internal assessment.

The Common Assessment Framework (CAF) method is used for public administration in order to define the level of fulfilment of criteria which have an influence on quality, so the CAF has become an important tool regarding quality improvement in public administration (Luczak & Wolniak, 2013). It was developed in 2000, under the authority of the Directors General of Public Administration of the EU member states in order to support the introduction of the idea and the principles of total quality management (TQM) in the public sector across the EU and beyond. The model was revised in 2006 and after that in 2013. It already has more than 2010 registered users (organisations that have implemented the CAF) spread in 38 countries, while it has been translated into 20 languages (Staes et al., 2010). Among the non-EU states working with the CAF are candidate members and neighbouring countries like Bosnia-Herzegovina, Croatia, Macedonia, Russia, Serbia, and many others (Patrick & Nick, 2010). The CAF may be applied in all types of public organisations regardless of the number of employees (Staes & Thijs, 2005). It has been designed for use in all parts of the public sector, and is applicable to public organisations at a national/federal, regional and local level (Thijs & Staes, 2006). Rickards (2013) showed the distribution of CAF users by sector in 2010, highlighting that local governments were the most represented.

The basic structure of the Common Assessment Framework has been derived from the European Excellence Model, although in a slightly modified way. The CAF thus handles a set of 9 evaluation criteria (figure 1): five criteria are used to assess the performance of the enablers, meaning what the organisation does in order to achieve excellent results, and then four criteria are directly used to assess the results that an organisation achieves.



**Figure 1:** CAF model structure (Vakalopoulou, 2012)

The CAF has been developed by making use of the "European Excellence Model" promoted by the European Foundation of Quality Management (EFQM), various national quality management tools derived from the Excellence Model and the Speyer Quality Award Scheme widely used in German-speaking European countries. One of the aims of the CAF is therefore to serve as a bridge between different quality management instruments and quality management cultures in Europe. It is not in competition with these instruments, but tries to complement them and to bring together their most important elements. The CAF is designed to be an easy-to-use tool for quality management in the public sector. It aspires to bridge the different quality models and to serve as a useful 'starter model' before moving on to more sophisticated quality management models (Van Dooren & Van de Walle, 2004). It is a simple, cost free and easy to use self-assessment tool (Vakalopoulou et al., 2012).

The most important reason to use the CAF is to identify a number of strong and weak points, which will then serve as a basis to set up targeted improvement actions (Dearing et al., 2006). On the other hand, many authors (Kelly & Swindell, 2002; Higgins, 2005; Wood et al., 2007; ) use the CAF performance for comparing with the customers' satisfaction. Taking this into account, as well as that any quality improvement should be directed according to customer satisfaction, the CAF model for three municipalities is examined in this paper, aiming at analysing the quality of three observed municipalities.

## 2. THE FRAMEWORK OF THE RESEARCH

For the requirements of the research, the CAF Scoring and assessment panels (2006) were used. An instrument for data collection was prepared for the purpose of scoring according to the CAF model.

### 2.1. Objective of the research

The basic objective of the research in this study is to determine and compare the results obtained using the CAF model related to citizens/customers in three municipalities. This would be a way to gain additional trust in the results obtained using the CAF model which refer to users of local self-governments. Moreover, the results obtained using the CAF model in this research can be compared with similar research for additional confirmation of their results.

### 2.2. Research questions

Based on the literature review, the following research questions are set out:

- A higher average score for each of the citizens/customers results for the local government obtained using the CAF model corresponds with a higher average overall CAF score;
- Municipalities with ISO 9001 certificate and higher maturity level gain higher CAF score comparing to the municipality without the certificate and low maturity level.

### 2.3. Research instruments

The first instrument was prepared according to the CAF fine-tuned scoring (2006 version) which served for data collection in order to determine individual scores for each component of the model relating to the work of local governments. The model was used according to the proposed structure of the criteria (Figure 1). The sixth criteria, "Customer results", was considered in detail in order to be able to compare the results with overall CAF scores. The following items were considered:

1. Results of citizen/customer satisfaction measurements (item 6.1 from the CAF model) – examples:

- Results regarding the overall image of the organisation (e.g. friendliness and fairness of treatment; flexibility and ability to address individual solutions);
  - Results regarding involvement and participation;
  - Results regarding accessibility (e.g. opening and waiting times, one-stop-shops);
  - Results relating to products and services (e.g. quality, reliability, compliance with quality standards, processing time, quality of advice given to the customers/citizens).
2. Indicators of citizen/customer-oriented measurements (item 6.2 from the CAF model) – examples:
- Indicators regarding the overall image of the organisation:
    - Number and processing time of complaints (e.g. resolution of conflict in cases of interest);
    - Extent of public trust towards the organisation and its services or products;
    - Waiting time;
    - Handling/processing time of services delivery;
    - Extent of employee training in relation to the effective handling of citizen/customer relationships (e.g. professionalism and friendly communication with, and treatment of, citizens/customers);
    - Indicators of complying with diversity and gender aspects;
  - Indicators regarding involvement:
    - Extent of involvement of stakeholders in the design and the delivery of services and products and/or the design of decision-making processes;
    - Suggestions received and recorded;
    - Implementation and extent of use of new and innovative ways of dealing with citizens/customers;
  - Indicators regarding accessibility;
  - Indicators regarding products and services:
    - Adherence to published service standards (e.g. citizens' charters);
    - Number of files returned with errors and/or cases requiring repeated processing/compensation;
    - Extent of efforts to improve availability, accuracy and transparency of information.

From the previous division it is noticeable that, in general, both items of this criterion (6.1 and 6.2) may be observed using the same 4 elements:

- Overall image of the organisation;
- Involvement and participation;
- Accessibility;
- Products and services.

During the scoring of the three municipalities according to the CAF model, the same team of appraisers used the following scale of scores:

- 0-10 points: No results are measured and / or no information is available.
- 11-30 points: Results are measured and show negative trends and / or results do not meet relevant targets.
- 31-50 points: Results show flat trends and / or some relevant targets are met.
- 51-70 points: Results show improving trends and / or most of the relevant targets are met.
- 71-90 points: Results show substantial progress and / or all the relevant targets are met.
- 91-100 points: Excellent and sustained results are achieved. All the relevant targets are met. Positive comparisons with the relevant organisations for all the key results are made.

## 2.4. Population and sample characteristics

Since this research is related to the views of citizens regarding the quality of the municipality services, it was necessary to place it in an appropriate situation in the municipality. This situation had to satisfy certain conditions, such as: a) offering a whole range of municipality services, so that all citizens were exposed to at least one of the services, b) being a unique institution for offering the services available to all citizens, in order to avoid confusion between different authorities, c) homogeneous delivery of the services in order to have similar levels of service available to all respondents, d) being a somewhat dense, urban type of population, in order to exclude distance from being an obstacle to the service experience, and e) interest of the municipality authorities. All the above stated conditions were met by three municipalities in Northeastern Bosnia and Herzegovina, with an estimated total population of 47,000 inhabitants.

For the purpose of researching the scores acquired using the instrument according to the CAF model, visits by the appraisal team were organized to each of the local areas during 2011 according to the given plan of assessment. The data were collected working with a selected team which included managers from particular

organisational units of the local governments. The work was organised through workshops and focus groups several times during the course of the project.

### 3. RESULTS

In order to facilitate the display of the data, abbreviated marks were assigned to the municipalities:

- A – for the municipality A (Municipality with no ISO 9001 certificate and low maturity level);
- B – for the municipality B (Municipality with ISO 9001 certificate and medium maturity level);
- C – for the municipality C (Municipality with ISO 9001 certificate and high maturity level).

Table 1 shows the results of scoring for the three municipalities according to the CAF model, where the average values of the scores are shown according to each criterion related to this model. The scores show the rank of the municipalities A-B-C, where the municipality A has the highest total score, as well as the highest scores for each individual criterion.

**Table 1:** Scores for the three municipalities according to all the items of the CAF model

	max	A	B	C	Relative	A	B	C
1. Leadership	400	45	66.25	147.5	100	11.25	16.56	36.87
2. Strategy	400	33.75	47.5	85	100	8.43	11.87	21.25
3. People	300	37.5	38.75	55	100	9.37	9.68	13.75
4. Partnership	600	135	138.75	151.25	100	33.75	34.68	37.81
5. Processes	300	43.75	53.75	123.75	100	10.93	13.43	30.93
6. Citizen results	200	20.75	28.75	34.375	100	5.18	7.18	8.593
7. People results	200	20	20	32.5	100	5	5	8.12
8. Society results	200	45	47.5	47.5	100	11.25	11.87	11.87
9. Key performance	200	70	72.5	77.5	100	17.5	18.12	19.37
<b>TOTAL</b>	<b>2800</b>				<b>900</b>	<b>112.68</b>	<b>128.43</b>	<b>188.59</b>

From the results shown, the same rank of the municipalities is observed for each of the items, and in total:

- Municipality A is the municipality with the lowest score (total of 112.68) and is therefore categorized as the worst municipality compared with the other two municipalities observed;
- Municipality B is the municipality with the middle score (total of 128.43) and is therefore categorized as the middle compared with the other two municipalities observed;
- Municipality C is the municipality with the highest score (total of 188.59) and is therefore categorized as the best municipality compared with the other two municipalities observed.

Table 2 has separate scores for the “Customer-related” item, which consists of two parts:

- Results of citizen/customer satisfaction measurements (item 6.1 from the CAF model);
- Indicators of citizen/customer-oriented measurements (item 6.2 from the CAF model).

**Table 2:** Scores for the three municipalities according to the items 6.1 and 6.2. of the CAF model

		A	B	C			A	B	C	
Citizen R	6.1.	<b>Trends</b>	26.75	26.75	27.75	6.2.	<b>Trends</b>	3	4	5.75
		<b>Targets</b>	6.5	19	27.5		<b>Targets</b>	5.25	7.75	7.75
			33.25	45.75	55.25			8.25	11.75	13.5
		<b>TOTAL</b>	16.63	22.88	27.63			4.125	5.875	6.75
Max 200	A	20.75								
	B	28.75								
	C	34.375								

Scores for the above mentioned 4 elements (Overall image of the organisation; Involvement and participation; Accessibility; Products and services) as the common elements of the two items (6.1 and 6.2) of “Customer-related” criteria can be found in Table 3.

**Table 3.** Scores for the three municipalities according to the common elements of the items 6.1. and 6.2. of the CAF model

6.1.		A	B	C	A	B	C
a. Overall image	Trends	31	31	31	Polling of the citizens performed through surveys on satisfaction from 2010. Not performed for 2011. Slight positive trends are stated in both surveys.	Polling performed for 2010 and 2011. Partial progress is present.	Polling performed for 2010 and 2011. Partial progress is present.
	Targets	11	31	40	There are no goals for 2010. In 2010 there is also a considerable portion of negative scores and answers. 26/40 of dissatisfied and very dissatisfied. There are no scores for 2011.	There are goals for 2010. Slightly greater portion of positive answers in comparison to S. Goals defined for 2011.	There are goals for 2010. Slightly greater portion of positive answers in comparison to B. Goals defined for 2011.
b. Involvement	Trends	10	10	10	According to the presented strategies and programs, certain matters concerning inclusion of citizens in decision making processes in local governments are present. There is no data on the degree of their realization.	The same as in case A.	The same as in case A.
	Targets	5	5	5	There are no objective indicators. Except estimations that are not results of systematic monitoring.	There are no objective indicators. Except estimations that are not results of systematic monitoring.	There are no objective indicators. Except estimations that are not results of systematic monitoring.
c. Access	Trends	35	35	35	Service Center opened	Service Center opened	Service Center opened
	Targets	5	5	5	There are no indicators	There are no indicators	There are no indicators
d. Services quality	Trends	31	31	35	Scoring performed for 2010.	Scoring performed for 2010 and 2011.	Scoring performed for 2010 and 2011.
	Targets	5	35	60	There is no data for 2011.	There is data for 2010 and 2011 with partially realized goals.	There is data for 2010 and 2011 with mostly realized goals.
Total	Trends	107	107	111			
	Targets	26	76	110			
Average	Trends	26.7	26.7	27.7			
	Targets	6.5	19	27.5			
6.2.		A	B	C	A	B	C
a. Overall image	Trends	6	6	10	There is data on complaints. Determination of their exact number is very demanding. There is no data on speed of their resolution. There are no other indicators.	There is data on complaints. Determination of their exact number is very demanding. There is no data on speed of their resolution. There are no other indicators.	There is partial data about other indicators as well, but it is not reliable.
	Targets	0	0	0	There is no system for defining and monitoring.		
b. Involvement	Trends	3	3	3	Unreliable data is partially present.		
	Targets	0	0	0	There is no system for defining and monitoring.		
c. Access	Trends	0	0	0	There is no data		
	Targets	0	0	0			
d. Services Q	Trends	3	7	10	Not very reliable and difficult to determine data on incompatibilities.	It is possible to determine the number of noncompliance. There is no data on monitoring and analysis.	It is possible to determine the number of non-compliant cases. There is certain data on monitoring and analysis.
	Targets	21	31	31	Recertification is not performed for 2011.	Recertification is performed as a goal for 2011.	Recertification is performed as a goal for 2011.
Total	Trends	12	16	23			
	Targets	21	31	31			
Average	Trends	3	4	5.7			
	Targets	5.2	7.7	7.7			

## 4. CONCLUSION

The CAF model is increasingly being used in different ways, one of which is to identify space for improvement, particularly in the public sector. However, this is an easier method in relation to other self-assessment management tools (such as EFQM Business Excellence Model, the ISO 9000 or 14000 series, Balanced Scorecard approaches, Six Sigma, etc.), which enables all organisations, regardless of their size, to perform self-evaluation. Therefore, the goal of this study was to evaluate and compare public administration quality including customer-related results.

Comparing the results obtained by the analyses in this study performed on both the total average values and individual elements of the noted models, it may be concluded that the ranking of municipalities regarding Citizens/Customers results is proportional to the overall CAF scores. Such results confirms the first research question set in this study. Therefore, the CAF model may be considered a sufficiently reliable method for obtaining data on real user satisfaction. In other words, based on this conclusion it is expected that as the customer-related CAF scores increase/decrease for a municipality it may be expected for the real degree of its user satisfaction to be higher/lower. This conclusion may be significant for the municipalities which have conducted or which regularly conduct self-assessment, but which are not able to examine their user satisfaction in a certain period in a direct way.

The analysis also showed that the CAF scores of three observed municipalities differ according to the maturity level. Results also confirms that the municipality with the high maturity level gains the best CAF score, while the municipality with no ISO 9001 certificate and the low maturity level gains least CAF score.

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