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THE DEVELOPMENT OF BUSINESS STANDARDIZATION AND INTEGRATED MANAGEMENT SYSTEMS

RAZVOJ POSLOVNE STANDARDIZACIJE I INTEGRISANI SISTEMI MENADŽMENTA

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Summary: At the beginning of the 21st century, business standardization has been experiencing intense development, while technical standardization has been moved to the background. Globalization, the development and application of IT technology, the global economic crisis and severe conditions in business have only contributed to this development. Today, the most current standards to be applied are ISO 9000, 14000, 17000, 18000, 20000, 22000, 27000, 31000 and others. At this point the basic question that arises is how to apply these standards in an integrated fashion. Integrated management systems are the answer, which should connect at least two standards or at best all of them – from five to seven. This paper deals with the development of individual models of business standardization, and their integration in the design and implementation of IMS, from the viewpoint of quality management requirements, environmental protection, the safety and health protection of employees and some other demands.

Keywords: business standardization, development, integration, management system, QMS, EMS, OHSAS, audit

Kratak sadržaj: Početkom 21. veka, poslovna standardizacija je doživela intenzivan razvoj, potisnuvši tehničku standardizaciju u drugi plan. Globalizacija, razvoj i primena IT tehnologija, svetska ekonomska kriza i teški uslovi poslovanja samo su doprineli tom razvoju. Danas su najaktuelniji za primenu standardi serije ISO 9000, 14000, 17000, 18000, 20000, 22000, 27000, 31000 i drugi. U ovom trenutku osnovno pitanje koje se postavlja je kako ove standarde primeniti integrisano. Odgovor su integrisani sistemi menadžmenta koji bi trebalo da povežu najmanje dva standarda, a najbolje bi bilo da to budu svi – od pet do sedam. Ovaj rad se bavi razvojem pojedinačnih modela poslovne standardizacije, kao i njihovom integracijom u cilju projektovanja i primene IMS-a, iz ugla zahteva za upravljanje kvalitetom, zaštitu životne sredine i bezbednost i zaštitu zdravlja zaposlenih, kao i nekih drugih.

Ključne reči: poslovna standardizacija, razvoj, integracija, sistem menadžmenta, QMS, EMS, OHSAS, audit

Instead of an introduction

Business systems in the first decade of the new millennium face new challenges in their operations, which are reflected in the following: (i) profitability, as the base paradigm of business in tough business conditions, (ii) competitiveness, as a condition for market survival, (iii) globalization, as a paradigm of global politics dictated by the strongest countries, (iv) the rapid change of business, as a consequence of globalization, (c) adaptability, as a condition for fast adaptation to changes, (vi) growth (request, population needs), and (vii) the development and application of advanced technologies (1–4). Management system standards, such as QMS (ISO 9001), EMS (ISO 14001), OHSAS 18001, FSMS (ISO 22000), SA, ISO/IEC 17025: 2005, ISO 15189:2003, ISO/IEC 27001:2005, ISO/IEC 17799:2005, ISO 13485:2003 and others, form a framework for the development and application of good management practices in organizations around the world. However, two conclusions can be drawn: (i) quality standards (QMS and their correspondent models) were the basis for the development of standards for other management systems, and (ii) three

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standards are most often found in practice today: QMS, EMS and OHSAS, providing more and more benefits when interconnected – integrated (IMS) (5–6). So, the question today is not whether these standardized models should be used, but how to use them together, as an integrated business system to be incorporated into an organization. Researchers and practitioners in this field are therefore concerned today with the issues of how to design, implement and improve the model of IMS. In (7) the general benefits of the application of IMS are described, such as: defining the responsibilities of the organization and the benefit to its stakeholders (customers, owners, suppliers, employees and society).

A number of partial management system standards (QMS, EMS, OHSAS) and/or those of non-standard type (manufacturing, financial, personnel, marketing, research) exist in every organization. Detailed analysis shows that companies are using between five and twenty different partial management systems in their operations. This often leads to complications in their business because of: (i) the complexity of information infrastructure, (ii) overlapping jurisdiction and responsibilities, (iii) the diversity of procedures for the same jobs, and (iv) the complexity of the organizational structure (8–11). Starting from these facts, the IMS in practice should provide the following: (i) cost reduction (internal audit, documentation, training, change of model in practice), (ii) reduction of time management/monitoring and reviewing management systems (single/multiple management systems), (iii) a holistic approach in the management of business risk (changes made outside of business conditions, easier to master the application of standard models in practice – business before application), (iv) reduction of duplicate requests/bureaucracy (integration of the same/similar request into the base of QMS), (v) avoidance of conflicts between different systems (resolution of possible conflicts of interest in the design phase, IMS), (vi) improvement of internal and external communications (integration of policies and goals between different management systems leading to improved communication), (vii) focusing on business process management (monitoring implementation of strategic objectives), (viii) improving motivation and relationships between employees (clearly defined responsibilities and authority, given in the models of standardized management systems, contribute to the implementation of these processes), and (ix) optimization of internal and external audits (one instead of several systems – the participation of competent people).

On the other hand, for effective application of IMS, the organization should perform the following: (i) risk management operations from the perspective of social protection, safety and health of employees, (ii) improve the effectiveness of operations, particularly manufacturing operations, (iii) reduce operating costs, (iv) improve employee/organization stakeholders satisfaction, (v) protect the brand and reputation of the organization, (vi) promote and implement innovations, (vii) remove any barriers to trade, (vii) establish a clear position for the organization on the market.

Today, these problems can be solved in different ways, namely through (i) the application and development of information systems based on computers, (ii) managers, their knowledge and experience, and (iii) the regulation of key management systems of partial operations and reliance on them. However, all these approaches have some defects. Consider the first one: an information system requires constant upgrading and investment in software/hardware, as this technology is rapidly evolving. On the other hand, for its successful development and implementation in an organization, constant investments are needed – in training and specialized personnel. What is the solution? The answer is – partial integration of management systems (12). This means taking what is crucial for the company from each partial management system and integrating these elements into one comprehensive – Integrated Management System. The following will be achieved: (i) better communication between the operating entities, (ii) improved work cooperation and process infrastructure, (iii) help in meeting customer requirements and implementation of quality requirements, and (iv) creating conditions where employees strive towards a total management system.

Research organizations are very old, almost as old as the human society, but in the past hundred years they have become particularly significant. Their founder was Frederick Taylor, the creator of scientific management, who defined the management of an organization as a key factor in the organization's survival. However, by the end of the seventies, there came about an explosion of ideas, theories, methods and techniques of management, so that we now find ourselves in the golden era of management. Changes in the world, especially in the final decade of the last century (13), necessitated the application of new management theories, which have agreed to new conditions. Today management is less skill and more science, based on the application of adequate methods and techniques. These should help in forming an organizational structure that will not be a physical set of functions and tasks for which managers are responsible who have their own – partial goals. An organization should, therefore, be established as an integrated system in which managers need to manage the relations between the elements, which are integrated over individual goals. So far, according to the classical theory, organizations have had hierarchical structures, but these have now become a limiting factor in their development and particularly in the implementation of new models for quality management, such as ISO 9001:2008, and process models. Hence, the increasing exploration of new directions for flexible organizational structures with a minimum number of levels has been viewed as the best option. These are lean systems, which represent the future of organizational models, primarily in manufacturing systems.

With the advent of ISO 9001:2008 and ISO 9000:2008, whose main features are process quality management and the models of excellence based on the concept of TQM, the conditions for partial integration and synergy management systems have been created. With the development of business standardization, processes have been moving in the direction of an integration model for quality management, environmental management, management of occupational health and safety of employees, and good manufacturing, laboratory and other business practices. On the other hand, standardized management systems do not show such intensive development, particularly from the point of application of new techniques and technologies.

Development of an integrated management system

Development of a management concept in an organization that will be compatible with the development of standardization of business processes is an issue that seeks to adapt to today's theory and practice of management. Another important issue is the increasing integration of non-standardized partial management systems into the current management concept of an organization. The goal is a total management system in which a high degree of synergy and harmony between the integrated parts is achieved, which should enable organizations to increase the level of excellence. Total Management System is a unique management model that includes general, specific and formalized (standardized) partial management systems.

There are three ways to develop a total management system:

(i) *addition* – within this approach to management, organizations develop special documents according to formalized models. Content (elements) and comparison of partial management systems is provided via a single reference list of these standards, on condition that the organization is certified. Conflicts involving the functioning and content of these systems are resolved, while each system is separately maintained.

(ii) *superstructure* is based on the fact that the organization takes a general management model or that of partial management of the system as a basis for building a unique model of an integrated and/or total management system. Such a connection provides documentation that is unique (common) at the level of instruction (work instructions), while the procedures and rules have common elements. Thus a model of an integrated and/or total management system is obtained in which the partial systems are easily identifiable,

(iii) *integration* – in this case an organization develops a generic management system as its own management system, which will include non-formalized and formalized management models (14–15). The integration process is not easy, especially because of the different structures of formalized management systems and their development as international standards. Another problem with this approach is the design, development and application of a generic management model for the organization, from which, on the basis of process integration and formalized and non-formalized management systems, information integration is carried out, the result of which is an integrated management model.

Developed and applied standards for management systems/products

The ISO 9000 series standards have been applied for more than two decades. Today, in organizations around the world, a number of standards and concepts for different management systems in the organization are being applied individually and/or collectively. Most of them have been developed and applied in the field of quality management. We can conclude here that the model QS/QMS was the basis for the development of many other models. Their short analysis shows that they include twenty-five standards or concepts. ISO 9000 is a series of standards for quality management systems, that was issued by the ISO that has 142 member national standards bodies. The model for certification of the ISO 9000 series standards – QMS is not a standard for some product or service, but refers to the process (system) which creates them. The character of these standards is generic so that they can be used in the entire world economy. They were issued in the year 1987, supplemented in 1994, and significantly amended in 2000. The newest model dates from the year 2008 (16). Today's version is ISO 9001/9004:2008 (2009), whose characteristics will be presented later. The most important features in the model ISO 9001:2008 are: its procedural structure, of a far more generic model with 20 elements of ISO 9001 in 1994, the PDCA cycle of continuous improvement, which is also used in ISO 14001, as well as its adjustment to the business management structure throughout an organization. QMS is applicable to all organizations that want to show their agreement to meet customer requirements for all categories of organizations, and we are now speaking of more than 1 million certificates of QMS worldwide. Certificate for QMS benefits the organization, because it objectively assesses the level of effectiveness of the established model for quality management, based on meeting the goals of quality and continuous improvement (17–18). It also allows the organization to be recognized in international relations as a reliable supplier. For example, ISO/TS 29001:2009 – Petroleum, petrochemical and natural gas industries, provides requirements for quality management systems and service organizations; IWA 1:2005 – Quality Management System, offers Guidelines for the improvement of health services; IWA 2:2007 – Quality management system/

application requirements of ISO 9001:2008 in education; IWA 4:2009 – Quality Management System/Guidelines for Implementation of ISO 9001:2008 in local government. QS-9000 standard was issued in 1994, as a replacement for ISO 9000, the major U.S. automotive supplier's trio: Daimler Chrysler, Ford and General Motors. It contains all the requirements of ISO 9001; in the year 1994, it was complemented by the sector-specific requirements of the Big Three, which stem from the special requirements of the motor vehicle industry. This standard applies to all internal and external suppliers of raw materials, semi-finished parts, components and services of the manufacturer, whose main goal is the provision of quality in the automotive manufacturing and quality assurance in the production of original auto parts. QS-9000 provided the application of continuous quality improvement, defect prevention and reduction of waste in the supply chain. General Motors and Daimler Chrysler require their supplier's certification under these standards, while Ford makes business compliance requirements (internal certification). This standard has been replaced with ISO/TS 16949:2009 – International Standard for QMS in the automotive industry. Adopted in 1999, it has been in revision since 2009 and has been harmonized with ISO 9001:2008. This standard integrates the requirements of ISO 9001:2008 with the specific requirements of the automotive industry such as the American QS-9000, German VDA 6.1, French and Italian EAQF AVSQ. Japanese and British car manufacturers also adhere to this standard, which applies to all internal and external suppliers of raw materials, semi-finished parts, components and services. The primary objective of this standard is the provision of quality in the automotive manufacturing and quality assurance in the production of original auto parts. In this way, the suppliers cooperate at an international level and coordinate the release of multiple certification audits by different standards in this field. The AS 9100 standard issued in 1999 has been in revision since 2009. The model is compliant with ISO 9001: 2008. It is a model for quality management of suppliers and sub-suppliers in the aviation industry and space exploration. This standard specifies the requirements for each department and each step in the manufacturing process regarding quality management in the industry. The requirements for the specification of parts and components for the design, installation, inspection and other characteristics of these products are also listed. Government agencies (USA), such as the Department of Defence (DD) and Federal Aviation Administration (FAA), also support the implementation of AS 9100. This model makes multiple controls and repeated requests redundant, so that it has essentially become the industry standard and government program in this area. Its application provides reduction of defects in the supply chain, continuous quality improvement and increased customer satisfaction. Certified organizations – suppliers have the advantage when drawing up a list of government suppliers of military procurement, and also those that meet the legal requirements in this area, which have become integral parts of these standards. The TL 9000 standard was issued in the year 1999, and its 2009 revision is compliant with ISO 9001:2008. It is a QMS model for the telecommunications industry, which harmonizes it with the requirements in the development, design, production, delivery, installation and maintenance of hardware, software products and services. Compliance with the requirements of TL 9000 reduces the time of appearance of these products on the market, as well as the costs in the supply chain of these products. The structure of TL 9000 includes five levels of requirements and measuring the effectiveness of QMS. These are ISO 9001:2008 requirements, joint requirements for QMS in the telecommunications industry, specifications for measuring the quality of services, hardware and software (18–19). TL 9000 Telecommunications specifications are divided into six categories, defined as: common (C), hardware (H), software (S), services (V), hardware and software (HS), and hardware and services (HV). As can be seen, demands for services and software (VS) have not been given. Suppliers in this industry require the application of additional elements relating to their production, while the hardware and software companies must seek to implement all sector-specific requirements. TL 9000 is also required to establish a model for measuring cost, performance and reliability of hardware, software and services. Performance measurement is particularly important from the customer point of view and includes: the level of return on investment in hardware, system output, the number of complaints, quality of new software, delivering on time, accuracy and reliability of the accounts and effectiveness of business processes of suppliers. Certification to this standard can be made for different levels of the organization, products and services, or a combination thereof. ISO standard 13485/88 is a QMS for medical devices. It has replaced the previous standard EN 46,001th. This standard was developed in 1993 by European manufacturers of medical devices as EN 46001/2 Quality assessment of medical devices, with additional requirements that apply to models of ISO 9001/2. The certification scheme EN 46001/2 was never developed, but is included in the ISO 9001/2 through additional requirements. Version of ISO 9001/2 from 1994 was released as EN 46001/2:1996, and since June 2001 it exists as a version of ISO 13485/88:1996. The latest version was released in 2009 and it is in accordance with ISO 9001:2008. ISO 13485:2003 specifies requirements for the QMS of the organization that produces medical devices, fulfilling the legal requirements and customer demands in this area. It has been developed and applied specifically to the certification scheme standards. QS (QMS) software has been used since 1994, instead of the standard ISO 9000-3, which was used in combination with ISO 9001/2. It is a model for quality assurance in developing, designing and using software and is oriented towards software companies that work

on its development. According to the British Department of Trade and Industry, the year 1998 was defined by the so-called TickIT procedures, which give the scheme for the implementation of QS requirements in designing and developing software for the certification of QS (SSCS – Software Sector Certification Scheme) and QMS examiners. TickIT Version 5.0, a version of the 2009 issue, is compatible with ISO 9000:2005, and provides a list of cross-cutting elements in ISO/IEC 12207:2008, which is a model for the lifespan of QMS-based software process, as well as for the standard ISO/IEC 15504, which defines the maturity model for a software product. ISO/IEC 17025 standard was issued in 1999, while a version compatible with ISO 9001:2008 was issued in 2009. It contains requirements for the accreditation of control and testing laboratories, which are related to the fact that they must produce evidence to work in the QMS, that they should be technically competent and able to generate technically valid results. All requirements of ISO 9000 that are relevant to the scope of control and testing laboratories, which are located in the QMS model, must be included in ISO/IEC 17025 as the technical requirements of competence. This standard includes materials related to a system of quality, qualified personnel, document management, review of requests, tenders and contracts, customer service, records management, testing and calibration of procurement, internal audit, environmental conditions, test and calibration methods and validation, equipment, measurement traceability, sampling, handling of samples for testing and calibration, data collection and reporting. The accreditation of a laboratory according to ISO/IEC 17025 is more important than certification to a QMS model, because it recognizes a competent laboratory that is capable of achieving technically valid results, which is more important than QMS compliance. In the case of a laboratory of a large system, it is recommended for ISO/IEC 17025 accreditation to work in parallel with the introduction of the QMS, in order to overlap the joint activities. ISO 14000 series of standards was released in 1996, while the new version is from 2009, and represents a global model for an environmental management system (EMS). Its application provides evidence that the organization is behaving responsibly towards the environment, or the means to control and manage all the parameters of production and technological processes that can disrupt the establishment of environmental parameters. EMS also provides a business agreement with international laws and regulations on environmental protection, prevention of hazardous situations, reducing waste and creating a positive image of an organization in the society. Organizations should certify the model ISO 14001 (EMS –Requirements with guidance for use), which demonstrates good management practice regarding environmental protection (20). The second model, ISO 14004:2004 (EMS system, the principles and supporting techniques), contains the elements that help an effective implementation of this system. This series also supports environmental labelling, life cycle assessment of products in terms of environmental protection, environmental aspects of product standards and evaluating environmental performance.

OHSAS 18001:2007 was developed by European standardization bodies, as well as the standard management system to protect occupational health and safety (OHSMS) (21). Its aim is to create a safe workplace. OHSAS 18001 contains the requirements for planning, risk assessment, hazard identification, consultation and communication, management and treatment in emergency situations. This standard is ideal for organizations that want to increase the safety of their employees, protect their health, and reduce medical treatment costs of injuries and provide sudden increase prevention in this field. Now we are negotiating with the ISO to make sure that in the future this standard is accepted and issued as an international standard. HACCP – hazard analysis and critical control points management model, was developed by the U.S. Department of Inspection and Control in Agriculture (FSIS) and its Food and Drug Administration (FDA). This model, under the same name, was later defined as the Danish standard. It represents, within a science-based approach, the means to access, control and eliminate contaminated and critical parameters/phenomena in the production and distribution of food. It is based on seven principles, which include: (i) establishing a critical analysis of possible processes, (ii) identification of critical points that should be controlled, (iii) the specification limits for these points, (iv) establishing procedures for their (control limits) monitoring, (v) establishing corrective actions, (vi) establishing procedures for verification, and (vii) establishing procedures for keeping records of these controls. HACCP requirements are accepted and supported by the United Nations (Codex Alimentarius), EU, Canada, Australia, New Zealand and Japan, and are used for meat, seafood, fowl, plants, mega-suppliers, restaurants and other food producers and suppliers. In our country, this standard became mandatory for food manufacturers in 2010. Since 2005, as a continuation of this standard international standards ISO 22000: 2005 – Food safety management systems/applications for organizations in the food chain, and ISO/TS 22004: 2005 – Food Safety Management Systems/ Instructions for the application of ISO 22000: 2005 have been developed and applied. They actually represent the integration of the HACCP system and ISO 9001:2008, which is the concept of quality management systems extended to food producers. In this way, the world system of certification of quality management systems for food producers has been established.

BS 7799 standard was developed by BSI, as well as the standard for protection management information system (ISMS). It can be applied in various business organizations, for information and communication systems and computer networks, and consists of two parts. The first one (7799-1) refers to the user and

the application of ISO/IEC 17799 (international standard for data protection). The second, BS 7799-2, gives the requirements of this standard and an audit model for its evaluation during application, and for the purpose of certification. The standard defines the requirements that are provided, as document management, policies to protect the organization, classification and management checks, physical security, communications management, managing compliance with statutory requirements. Successors of these standards are the standards ISO/IEC 27001:2007 – Information Security Management Systems/requirements, and ISO/IEC 27002:2007 – Best practice information security management, which was formally succeeded by ISO 17779:2005. According to these standards, there is today a system of certification and ISO/IEC 27006:2007 defines requirements for the certification bodies and assessment bodies under this standard. ISO 20000-1:2005 is the standard for service management in IT technology. It defines the requests for this service, developed based on the QMS model. It is used in pairs with ISO 20000-2:2005, which defines the user evaluation of the implementation of the first standard and its enhancements. These are a different group from a whole series of standards related to ICT technologies, which include: design and software development, IT service management and security and protection of information systems.

SA 8000 standard was issued in 1997 (by the international organization for social responsibility and its economic priorities for the Council) and was the first international standard on social responsibility to employees. A new version was made in 2002. It requires employers to guarantee basic worker rights for employees, provide safe working conditions, prohibits child labour and postulates a regular workweek of 42 hours. Other requirements of SA 8000 are related to health care, the right to join trade unions, prohibition of discrimination on religious, racial and ethnic grounds, as well as the opportunity for advancement in the profession. It was developed by the Council for Economic Development (CEPA), with a wide range of business, industry, trade unions, human rights organizations, the UN and others. SA 8000 promotes the improvement of working conditions and social protection in the conditions of the globalization of world economy. With certification under this standard, the company provides a positive image and reputation among its customers, employees, suppliers, owners and customers, the best practices of social protection of employees and the conditions of their work. This has often resulted in extremely high product quality organizations that are certified under these standards. In 2007, Institute for Social and Ethical Responsibility made a standard AA 1000 – Standard for the ethical performance of organizations that promote the development and promotion of ethical norms of business. ISO/IEC 15408 standard was issued in 1999 as the first international standard for information technology, which defined the criteria for evaluating security products of these technologies such as operating systems, computer networks, distribution systems, application of hardware, firmware and software. The requirements of this standard are specified as functions of IT products and systems security, as well as measuring the level of protection and security validation. Common Criteria (CC) can also be used as a guide for users, as well as those working on the development of these products. During the validation and evaluation of IT products used by the target criteria (TOE), a set of specifications and requirements for protection can be assessed along with validation of TOE in the development of conservation objectives (ST). Application of a set of independent requirements from the category TOE can consider the specific requirements of customers/users from the perspective of the so-called members of the protected profile (PP). Evaluation and validation of the evaluation are done using the requirements of the PP, ST, TOE and CC. ISO/IEC 15408 CC is applied in the USA through the National Agency for the Provision of Information (NIAP), the National Scheme for the Assessment of Common Criteria (CCEVS), which together with the standard constitute the whole product review and accreditation of national laboratories for research in this area. The latest version of these standards is ISO/IEC 15408-1:2005/Criteria for evaluating IT security products.

BS 6079-3 is a standard issued in 2002 that refers to the risk management in business projects. It describes risk management as a primary process in any organization, regardless of the size, activity and sector of activity. It defines good practice for risk management, including: risk identification, risk analysis, assessment and risk control. This standard also defines three levels of decision making in relation to risk: strategic (long-term goals), tactical (medium risk) and operational level (short-term risks). The essence of the standard is to identify risks at an early stage of project planning. Standards for the same area were released in the U.S., Canada and Australia, and a new ISO international standard in this area – ISO 31000:2009 has been recently issued. This is a standard for risk management, which will help to get through a standardized management system in order to begin to manage risk business processes in the organization. Supply Chain Management recognizes competent networks of supply chains rather than individual companies. These form a network company that connects suppliers and buyers in the product lifecycle, from raw material to its exclusion from the process of use. Supply Chain Management integrates all the aspects of development and design and competitive production, and the use of a product during its lifespan. This model optimizes and synchronizes the material, process, information flows from raw material to products delivered to customers, optimizing the inventory and reducing the costs of product life. The rule is: to deliver

the product at the right time to the right place with the right (affordable) cost for the customer. Each organization in the supply chain can initiate the program and realize the benefits of it. However, the organization that is closest to the end user is as a rule best positioned in the supply chain. Today, two standards are used for this purpose: (i) ISO/PAS 28000:2005 – Requirements for management system safety in the supply chain, and (ii) ISO/PAS 28003:2006 – Requirements for management system safety in the supply chain/Requirements for certification bodies and assessment bodies according to ISO/PAS 28000:2005.

CE mark is a sign of quality products, required for the export of certain types of products in the EU. It defines the New Approach Directives required in EU countries (15 old + 10 new member states + 2 newest members) and in four countries outside the EU that are members of the European Free Trade Association. The above directives are designed to eliminate technical barriers to trade in Europe and to ensure that products are safe for use. Their most important application is related to medical devices and toys, but they are used in the manufacture of electrical equipment, machinery, electromagnetic compatibility, terminals, tanks, explosive and radioactive devices, and personal protective equipment. The mark is assigned to a product after an evaluation of its properties, which should be compatible with the requirements of these directives. CB certification is a safety test necessary for a product to be used and defined by IEC standards (electrical and electronic defined IECE CB scheme). It promotes global harmonization and elimination of trade barriers. Tests according to this scheme are carried out in accredited laboratories, using verified methods, according to the required IEC standards and generally have a certified QMS (ISO 17025). VCA certification is a system developed in the UK for the European automotive industry and is a model of quality evaluation of components that are installed in the automobile industry (glass, electronic equipment, mirrors, belts, signal blinkers), according to EC Directives and UN/ECE regulations. This symbol refers to the safe and reliable use of these components and is usually part of the Certified QMS system (9001 or 16949) and EMS. Today it is widely used in the automotive industry of North America and the Far East. ENEC mark is a European certification system for products which are used as components in the IT products (connectors, LEDs, capacitors, etc.). Testing of these components is done in authorized laboratories, in terms of electrical safety and their performance in different conditions of exploitation. Also, these tests may include the production processes, if the characteristics of the product so require. Kitemark is the oldest symbol of quality products, established in England back in 1902. Today it is awarded as a mark of quality to products, processes and systems and currently covers about 60% of products for human consumption, which are placed on the EU market. By its characteristics, it was the forerunner of ISO 9000 (quality system applied to the whole business system), and kitemark – a system of product quality (process/system with which to get the right product). It has turned to the exclusive protection of consumers regarding the quality of products, so today it is mainly seen in couple with ISO 9001:2008.

Good Manufacturing Practice (GMP) is a set of procedures that must be applied by the manufacturers of medical devices and drugs who want their products to be placed on the USA market. They were laid down by the already listed agency FDA (Food and Drug Administration), and an organization is required to establish a quality assurance program for its medical devices, according to the specifications that ensure control over their safe and effective use. CGMP completes the program of quality assurance in an organization, investigating buildings, equipment, components, manufacturing and production processes, packaging and labeling, distribution and installation, maintenance and cleaning equipment and records. The auditors assessed the FDA approval of bills with CGMP quality assurance plan. Besides this, there are also good practices in the pharmaceutical, food and beverage industries: laboratory, packaging etc.). Along with these systems for the certification of management practices, products or processes, based on national and/or international standards, there are many others like: IECQ-CECC CEN mark, GOST R sign, RADMAC sign, ASTA gold sign, beagle sign, S sign, GS symbol, ETL and CCC mark sign, which in fact represent a sign of quality products and relate to the fulfilment of specific standards for these products. Today, all of them, as a rule, are applied in pairs with ISO 9001:2008.

ISO 9001:2008 – General characteristics

In June 2007, ISO TC 176 decided that the CD version of the ISO 9001 translates the DIS version (September 2007), after which a public discussion followed until the endof February 2008. In the first half of 2008, ISO 9001:2008/FDIS version was on the scene, until late summer of that year when a vote was adopted, and on November 15th, 2008, a new version of ISO 9001:2008 was officially declared (18). The underlying idea for TC 176 in relation to the audit models 9001 and 9004 from the year 2000 was: (i) the development and consistent application of the model of continuous improvement for users, (ii) improving the consistency of the ISO 9000 family, and (iii) improving compatibility with ISO 14001: 2004. After analyzing the new version of QMS in detail, it can be concluded: (i) the basic structure of this model has remained the same compared to the previous version from the year 2000, (ii) the nature of the changes is such that substantial changes in the certified system will be required (as was the case with the versions of 1994/2000), and (iii) the whole QMS system, as a certified model, will in future be based on the same

grounds as the previous version. Changes (cosmetic/linguistic in nature) in the most recent model are related to: (i) item 0.2 (Process approach), (ii) item 1.1 (general), (iii) item 4.1 (general requirements), (iv) item 4.2.1 (documentation), (c) item 4.2.3 (document management), (vi) item 4.2.4 (records management), (vii) paragraph 5.5.2 (liability management), (viii) paragraph 6.2.1 (resources employed), (ix) item 6.3 (infrastructure), (x) item 6.4 (working conditions), (xi) item 7.2.1 (processes related to the customer), (xii) paragraph 7.3.1 (planning design and development), (xiii) paragraph 7.3.3 (out of design and development), (xiv) point 7.5.4 (property buyer), (xv) item 7.6 (control and monitoring of measuring equipment), (xvi) item 8.2.1 (satisfaction customer), and (xvii) item 8.2.3 (monitoring and measurement processes).

ISO 9004:2009 – Basic characteristics

This standard was named according to an earlier version – ISO 9004:2000/Instructions for improving performance (20). The new version, which appeared in 2007, and whose official announcement came on October 15, 2009, has the name ISO 9004:2008/Management of sustainable business success. The instantly recognizable name introduces a new concept of these standards based on a completely new approach to sustainable development based on QM. It is obvious that things related to economic development move toward sustainable development – the paradigm of business at the beginning of the 21st century. On the other hand, this means that the model of QM, inaugurated by the ISO 9001:2000 (2008) remains as a future model of quality management that will not be changed in the near future, and that its promotion goes towards the integration of sustainable development, business excellence and integrated business assurance (which at present consists of integrated management systems). All these facts support the new structure of ISO 9004:2008, which includes: (i) item 3 – the definition of sustainable development (organization is able to maintain and develop its performance over a longer period of time), (ii) item 4 – Management of sustainable development (4.1/general; 4.2/key features of sustainable development (organization); 4.3/management of sustainable development, 4.4/evaluation of sustainable development, (iii) item 5 – Environment Organization (5.1/general; 5.2/monitoring; 5.3/analysis), (iv) item 6 – strategy, policy and communications (6.1/strategic orientation; 6.2/mission and vision; 6.3/aspects of the strategy; 6.4/policies and objectives; 6.5/strategic planning; 6.6/risk management; 6.7/review strategies for sustainable development; 6.8/Communications (6.8.1–general, 6.8.2–effectiveness and efficiency of the process of communication)), item 7 – Resources (7.1/resource management; 7.2/planning; 7.3/resource allocation; 7.4/resources staff (7.4.1–general, 7.4.2–motivation and involvement of employees); 7.5/infrastructure (7.5.1–general, 7.5.2–working conditions); 7.6/knowledge; 7.7/financial resources; 7.8/natural resources management and life expectancy; item 8 – processes (8.1/process approach; 8.2/types of processes; 8.3/management processes of the organization; 8.4/responsibility and authority for the process); item 9 – Measurement and Analysis (9.1/measurement approach; 9.2/performance matrix, 9.3/measurement of achieving the goals; 9.4/key indicators; 9.5/tools for measuring; 9.6/internal audit; 9.7/evaluation; 9.8/review and evaluation process); item 10–Learning, improvement and innovation (10.1/general; 10.2/learning (10.2.1–types of learning, 10.2.2–sources of learning, 10.2.3–factors that influence the effectiveness of learning, 10.2.4 – planning of learning), 10.3/improvement; 10.4/innovation (10.4.1 – generally, 10.4.2 – Types of innovation, 10.4.3 – factors that influence the effectiveness of innovation, and 10.4.4 – Planning process innovation) Appendix A – Tools for assessing the maturity (A.1/introduction; A.2 Description of the level of maturity; A.3/Assessment Strategy; A.4/Mark work; A.5/tools for evaluation; A.6/results evaluation and improvement planning), and Appendix B – Forms estimation of the level of maturity. The above structure allows us to define the following conclusion – keywords in the new model to improve QMS are: sustainable development, the maturity level of QMS, learning and innovation. This brings special challenges for our businesses, but the opening of our country and the arrival of foreign companies that bring new business practices based on these fundamentals will cause these fresh concepts to be increasingly applied in our country.

PAS 99:2006 – Basic characteristics

This guide is a recommendation of the BSI-I for the integration of QMS, EMS, OHSAS, ISO/IEC 20000, ISO 22000 and ISO/IEC 27001, based on common elements and uses that every user who puts this document into practice can achieve (7). It was created on the basis of a document (19) that first defined the framework for the integration of standardized management systems. The intention of the ISO, then and now, was to promote business standardization, while at the same time respecting the achieved level of organizational development of each individual business system. The basic framework for the integration is comprised of: (i) policies, (ii) planning, (iii) implementation and operations, (iv) assessment of performance, (v) improvements, and (vi) management review.

Why are integrated management systems important?

At this point an integrated management system is considered the key concept for future business systems. However, partial management systems are dominant in

practice. The main reason lies in the fact that so-far standards have only been developed for them, since partial management systems are being developed in accordance with these standards or based on them. Functions and departments in an organization have also been organized separately, which means that emphasis is placed on their improvement and not on improving their relationships. Therefore, it follows that an integrated management system has a highly complex structure and complex relationships. In the last decade, however, things have been changing in this area, especially due to the following facts: (i) increase in the number of partial systems established in an organization, which increases the potential for conflict and reduces the effectiveness of an organization, and (ii) problems in the parallel implementation of several individual management systems, which can lead to the following: (a) comprehensive character of the goals, tasks and problems are covered up, (b) identical procedures are developed in different parts, which results in predisposition towards conflict situations, (c) problems in coordination are largely present, (d) the organization is exposed to additional costs, such as maintaining records and performing checks, (e) leads to loss of information, and (f) individual systems sometimes confuse employees; (iii) the occurrence of the version of ISO 9001:2008 QMS based on process approach, and (iv) more talk about integrated management systems (5–10).

On the other hand, there are many factors that support IMS integration: (i) if properly designed and implemented, the IMS will have a lower cost than separate systems, and will also facilitate the decision-making processes, particularly those relating to the entire organization, (ii) objectives and management processes are basically the same, (iii) integration leads to avoiding repetition of procedures and processes, (iv) integration reduces the possibility of solving the problem at the expense of creating new problems in other disciplines, (v) driving the activities of one element of IMS initiates other elements that would otherwise have died down, (vi) expertise in each specialty is gathered more quickly to generate responses to relevant questions, (vii) an IMS can reduce irregularities in the allocation of resources in separate systems, and (viii) a positive attitude from a management system can be effectively transferred to other management systems.

Approaches to integrated management systems

An IMS is a single, comprehensive organizational and management concept of an organization. It provides the necessary combining and linking of the existing, subject-oriented, individual management systems. Of particular importance is how the integration is understood and implemented in practice. The primary issues in the integration of partial management systems are: (i) which partial management systems are being integrated, and (ii) what does integration imply, especially considering the following facts: (a) whether integration is the only way to exchange information between individual systems, (b) the allocation of powers and responsibilities, (c) forming of unique procedures and work instructions, (d) defining the overall responsibility management, and (e) appointing one representative from management; (iii) what integration should look like. Here we consider the following cases: (a) system integration and the differences between individual systems (goals, architecture), and (b) whether the concept of integration is suitable for application. Several approaches to integration are now being used in practice, depending on the current position of the organization: (i) conversion – if the organization has certified QMS, it can be upgraded by adding the necessary process to meet the requirements of the standards of other partial management systems. Integration is carried out by adding a new practice to the existing processes. The disadvantage of this approach is that the quality of results depends to a large extent on the initial QMS that has been certified; (ii) fusion system – if the organization has certified more than one system, then it can connect them and continue to integrate other systems. In this way, organizations can bring together documentation where it supports the same processes; and (iii) system engineering – whether or not the organization has existing formalized or non-formalized management systems, system engineering can be applied to manage the development of the system. The advantages are that the organization can develop a coherent system that serves to further enhance its business and that it does not bind the organization to a certain standard. Standards are used to assist in identifying activities and processes.

An approach to the development of a standard model for IMS

On the one hand, there has been a lot of talk about the development of standards for IMS, and on the other hand, many organizations are trying to enforce them, in an attempt to meet the requirements of ISO 9001, ISO 14001 and OHSAS 18001. What users today lack is a clear structure of the new IMS and a course of action that will allow certification without major problems. Therefore, the logic solution today is the development of uniform standards for IMS, which will cover the subject area and all three of these standards (23–27). The importance of ISO 9000 is growing every day, and the number of certified organizations has reached around 1 million worldwide. Certified organizations are recognized by the fact that their products have distinctive quality. In this way, increasing customer satisfaction will increase sales and profits. Setting up the strict requirements of the ISO 9001 standard sends a strong message that the

organization takes quality seriously. Modern product development makes it a priority to secure requirements for environmental protection through regulations prescribing allowable emission limit values for various environmental pollutants. The results of this practice are especially seen in the increasing use of standards for environmental protection – ISO 14000. From the standpoint of successful business, demands for occupational health and safety become even more significant. The standard for Management System Occupational Health and Safety – OHSAS 18000 enhances company image by reducing employee health and safety risks. It also helps to reduce costs and leaves, prevents unsafe health and safety conditions, assists in the correction of possible incidents or emergencies and objectively shows respect for ethical and social values. Similarity within the structures of ISO 9001, ISO 14001 and OHSAS 18001, allows the integration of their information, which is achieved through the matching of the degree of key principles on which these standards are based, namely: (i) an understanding of the business processes, (ii) leadership (iii) measurable goals, (iv) customer satisfaction, (c) human resources management and development, (vi) employee satisfaction, (vii) performance testing and continuous improvement, (viii) effective communication, and (ix) effective measure.

These three standards are also mutually complementary, as they are applicable regardless of the nature of products and type of organization. In addition, the application of IMS leads to substantial improvement in business efficiency and quality of products and processes. The basis for the integration of ISO 9001, ISO 14001 and OHSAS 18001 in a single standard for IMS provides a process model that is called QMS. ISO 9001:2008 defines the process as a system of activities that uses resources to transform inputs into outputs. In doing this, the activity is considered to be using the resources, performing the transformation of inputs into output. A process approach establishes a link between outputs and inputs, because only feedback, through verification of outputs in relation to input requirements, provides a basis for process adaptation with the aim to satisfy customers and all interested parties. A version of the standard for QMS uses as a management model the cycle of continuous improvement, based on the PDCA concept. From the perspective of integration of these three models, the aspects of the PDCA cycle are as follows: (i) P (plan) (a) integrated policy – (1) policy management model, (b) plan – (1) identification and evaluation of aspects, impacts and risks, (2) identification of legal and other requirements, (3) planning, (4) goals, (5) organization, powers and responsibilities, (ii) DO – (a) implementation and operations – (1) management operations, (2) resource management, (3) requirements for documentation, (4) communication, (iii) CHEK – (a) evaluation of performance – (1) monitoring and measurement, (2) to evaluate and compare, (3) internal audit, (4) non-conformity management, and (iv) ACT (application/improvement) – (a) management review – (1) general, (2) inputs, (3) outputs, (b) improvements – (1) general, (2) corrective and preventive action and improvement.

Therefore, the development of standards for IMS starts with the QMS, as a basis for the integration and development of an IMS model. Thus, the standard for IMS includes a flexible basis made up of elements that are associated with additional requirements for the system of environmental management and Occupational Health and Safety management system. A flexible basis implies a core of the integration, that each organization can choose and define for itself.

The IMS standard (28–37) consists of parts A and B. Part A is called the main part of the standard and contains the required parts (elements) of the IMS, related to the implementation and continuous improvement of the common elements of IMS. Part B contains additional elements of particular management systems. Using core integration to establish a cross connection between the elements and their integration, it forms the skeleton of the IMS. Management processes form the basis of modeling, as is the case with the QMS. Part A contains eight sections, namely: (i) scope, (ii) links with other standards, (iii) terms and definitions, (iv) requirements for IMS, (v) accountability of management, (vi) management of resources, (vii) implementation, and (viii) measurement, analysis and improvement. The introduction describes the model of IMS. Requirements for IMS are described in the fourth module, and they include the general requirements and requirements related to documentation. The fifth module defines the powers and responsibilities of top management, the establishment of policy and quality objectives, management review. Here, the suitability, adequacy and effectiveness of the IMS are examined. The sixth module is a model of resource management in the organization, relating to infrastructure and employees. Product realization is described in the seventh module, and refers to the operations and activities during realization that are necessary to plan, including specific environmental and health risks and the safety of employees. The eighth module defines the requirements for measurement and improvement, through the established procedures of inspection, audit, internal audit, internal and external communications, corrective and preventive measures. Part B contains requirements for additional, different management systems, which make up the overall structure of the IMS, namely: (i) a system of environmental management, where a framework for building models to meet the demands for environmental protection is defined, as well as internal goals of the organization related to this issue, and (ii) management system of occupational health and safety of employees, which provides a framework for models for the fulfilment of statutory and other requirements in the identification of potentially hazardous situations

and defines the establishment of action plans for their prevention and control.

So, these are the key management systems covered by this standard, which should be handled according to its demands, that must be documented, continuously improved and reviewed. Also, the organization has the freedom to choose the basis from which to begin the application of the required IMS, from the perspective of politics and culture of the organization. However, harmonization in the development of IMS, which may be necessitated by requirements for individual management systems, can best be overcome through audits. This means that the next task in developing IMS standards will be to develop a model audit for it, as has been achieved for QMS and EMS. This model should facilitate its implementation, and therefore increase its effectiveness, as well as its simplicity and uniformity. Current models of management organizations are moving towards the development and application of cross-functional types of organization, providing connectivity between different specialties within the organization. This standard should enable the development of standard terminology for these management systems. First of all, it should ensure that the unique objectives that permeate the different management systems are better understood, monitored and verified. Application of this standard requires a new management structure of the organization, which is partly a matter of application of these standards.

Instead of a conclusion

With the presented IMS model in mind (13–6) and regarding the development of a standardized management system, we could draw the following conclusions: (i) globalization of the world economy requires that products on the world market satisfy specific requirements, and above all have high quality, (ii) international economic cooperation requires regulated business systems, especially those operating under the requirements of appropriate standards, and (iii) the lag of our economy in these areas is now an obstacle to our faster connection with the integration process in the world.

Conflict of interest statement

The authors stated that there are no conflicts of interest regarding the publication of this article.

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