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**DISTINCTIONS AND FEATURES
 OF ISO 9001:2015 STANDARD
 IMPLEMENTATION IN THE CONTEXT OF
 SOCIAL AND STRATEGIC DEVELOPMENT
 OF ENTERPRISES**

Urgency of the research. In terms of globalization of business and trade, when even the concept of "crisis" becomes global, the desire for continued growth and development becomes the most important and top priority.

Concerning this, questions about more efficient, rational management, certification, quality management systems, including the ISO 9001 standard arise lately.

Target setting. The quality and quantity of products are the most important indicators of the final result of the enterprise. Therefore, one should keep in mind the strategic importance of the tasks to be solved such as moral, social and political aspects not only organizational, managerial, economic, technical, industrial and consumer aspects of the problem. The problem of improving quality should be a state priority.

Actual scientific researches and issues analysis. Such well-known scientists as A. Glichev, M. Kruglov, I. Kryzhanivsky, A. Lositsky, T. Korneeva, E. Korotkov, A. Feigenbaum, G. Taguchi, E. Shilling, H. Wadsworth, T. Seifi, Y. Rebrin has made a significant contribution to the development of the theory, methodology and history of product quality management.

Uninvestigated parts of general matters defining. At the same time very few of scientific papers highlights the peculiarities of quality management systems based on the new version of the ISO 9001:2015 international standard implementation. New requirements of this standard as well as its differences from the previous version require researching.

The research objective. To study the features of the new version of the ISO 9001:2015 international standard, compare it with the previous edition of ISO 9001:2008 one and highlight the key differences.

The statement of basic materials. In the article the peculiarities of implementation of the ISO 9001:2015 standard are considered. A comparative characteristic between versions of the 2008 standard and 2015 one is conducted. It is established that the main differences concern principles of quality management, structure of the standard, terms and definitions, requirements of the standard.

Conclusions. The ISO 9001 certificate for the quality management system does not guarantee the quality of the product or service provided. Designing and obtaining the ISO 9001 certificate serves as a kind of trust instrument.

Keywords: ISO 9001:2015; ISO 9001:2008; quality management system; risk; process.

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**ВІДМІННОСТІ ТА ОСОБЛИВОСТІ
 ВПРОВАДЖЕННЯ СТАНДАРТУ
 ISO 9001:2015 В КОНТЕКСТІ СОЦІАЛЬНОГО
 ТА СТРАТЕГІЧНОГО РОЗВИТКУ
 ПІДПРИЄМСТВ**

Актуальність теми дослідження. В умовах глобалізації бізнесу та торгівлі, коли навіть поняття «криза» набуває світового характеру, прагнення до постійного зростання і розвитку стає найбільш важливим і першочерговим.

У зв'язку з цим, останнім часом, виникають питання про більш ефективне, раціональне управління, сертифікацію, системи управління якістю, в тому числі стандарт ISO 9001.

Постановка проблеми. Якість і кількість продукції є найважливішими показниками кінцевого результату діяльності підприємства. Тому слід мати на увазі стратегічне значення вирішуваних завдань: не тільки організаційно-управлінські, економічні, технічні, виробничо-споживчі бою проблеми, а й моральні, соціальні і політичні аспекти. Проблема підвищення якості повинна стати державним пріоритетом.

Аналіз останніх досліджень і публікацій. Значний внесок у розвиток теорії, методології та історії розвитку управління якістю продукції зробили відомі вчені: А. Глічев, М. Круглов, І. Крижанівський, О. Лосицький, Т. Корнеєва, Е. Коротков, А. Фейгенбаум, Г. Тагучі, Е. Шілінг, Х. Вадсворт, Т. Сейфі, Ю. Ребрін.

Виділення недосліджених частин загальної проблеми. У той же час недостатньо наукових праць висвітлюють особливості впровадження систем управління якістю на основі нової версії міжнародного стандарту ISO 9001:2015. Потребують дослідження нові вимоги, визначені даним стандартом, а також його відмінності від попередньої версії.

Постановка завдання. Дослідження особливостей нової версії міжнародного стандарту ISO 9001:2015, порівняння його з попередньою редакцією ISO 9001:2008 та виділення ключових відмінностей.

Виклад основного матеріалу. У статті розглянуто особливості впровадження стандарту ISO 9001:2015. Проведено порівняльну характеристику між версіями стандарту 2008 року та 2015 року. Встановлено, що основні відмінності стосуються: принципів менеджменту якості, структури стандарту, термінів та визначень, вимог стандарту.

Висновки. Сертифікат на систему менеджменту якості ISO 9001 не гарантує якості виробленої продукції або наданої послуги. Оформлення та отримання сертифікату ISO 9001 служить в якості своєрідного інструменту довіри.

Ключові слова: ISO 9001:2015; ISO 9001:2008; система управління якістю; ризик; процес.

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Urgency of the research. Improving product quality in a competitive environment is one of the most important and challenging tasks for any manufacturer of goods and services. The problem of quality is particularly acute at the present stage of market relations development, when domestic producers have to face fierce competition not only on the external market, but also on the domestic one.

The economic reforms are undertaken, the gradual transition from the producer's market to the buyer's market, to the protection of consumer rights raise sharply the question of clarifying the methodological foundations of product quality management.

Target setting. In current economic conditions the main task of enterprises is to increase competitiveness in the market. Every day the number of companies is growing, small and medium businesses are developing so it is necessary to introduce the latest management systems and organizations in order to survive in such conditions. The practice of financial and economic activity of enterprises shows that companies specializing in one sphere and having approximately equivalent financial and material resources quite often receive different profits. As a rule manufacturers financial prosperity can be achieved only with high-quality and competitive products or services. Problems of quality, competitiveness and quality control become a key factor for Ukrainian organizations. This lead to a high growth of interest in strategy of quality issues and search for methods and approaches to address them.

Currently, there are many different methods and approaches to assess the effectiveness of quality management systems. The main provisions for evaluating the effectiveness of the quality management system are described in ISO 9001 standards. First of all, this relates to the activity of the management for the analysis and further improvement of the enterprise quality system.

Actual scientific researches and issues analysis. Famous scientists made a significant contribution to the development of the theory, methodology and history of product quality management Among them are A. V. Hlichev, M. I. Kruhlov, I. D. Kryzhanivskyi, O. H. Losytskyi, T. V. Kornieieva, E. M. Korotkov, A. Feigenbaum, G. Taguchi, Ye. Schilling, H. Wadsworth, T. F. Seifi, Yu. I. Rebrin.

Uninvestigated parts of general matters defining. At the same time, few scientific papers highlight the peculiarities of implementing quality management systems based on the new version of the international standard ISO 9001:2015. New requirements defined by this standard need the research, as well as their differences from the previous version.

The research objective. To study new version features of international standard ISO 9001:2015 comparing it with the previous edition of ISO 9001:2008 and highlighting the key differences.

The statement of basic materials. The ISO abbreviation stands for International Organization for Standardization. This is an organization that is a worldwide federation of national standardization organizations.

ISO standards were first introduced in 1987. After that every 6-7 years the standard is reviewed and refined. For today, five versions have already been released, with the latest ISO 9001:2015 being released in September 2015 (Tab. 1).

Today more than 150 countries in the world are ISO members which are represented by national standardization organizations. More than 17,000 international standards were published in various fields of activity during the period of the organization the existence. The beginning was laid in the period of rapid production rise and, as a consequence, a powerful development of trade between large industrialized countries. The introduction of standards led to cheaper products, reduced production costs, reduced waste, improved compatible products produced in different countries, simplified use and maintenance. To date, more than one million ISO 9001 certificates have been issued worldwide in more than 100 countries.

ISO 9001:2015 contains the basic concepts, principles and vocabulary of quality management systems. Also it is the basis for other quality management system standards. This standard does not specify product / service requirements.

On September 15, 2016 the International Standardization Organization adopted a new version of ISO 9001:2015 standard. Since then, a transition period of 3 years has begun, during which both the

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old version of the standard ISO 9001:2008 and the new version of ISO 9001:2015 certificates have been valid.

Table 1

Main stages for ISO* version standards development

Year	Standard
1987	Adoption of the first group of series standards (ISO 8402, ISO 9000, ISO 9001, ISO 9002, ISO 9003, ISO 9004)
1994	Adoption of the revised version of standards group, on which the certification of the quality management system is carried out (ISO 9001, ISO 9002, ISO 9004)
2000	Review the key standards of this series (ISO 9000, ISO 9004), the reduction of standards number for carrying out one appropriate standard (ISO 9001)
2002	Adoption of ISO 19011:2002 standard concerning audits of quality management systems and environmental management systems
2005	Updated edition of ISO 9000:2005 standard release
2008	Updated edition of ISO 9001: 2008 standard release
2009	Updated edition of ISO 9004: 2009 standard release
2011	Updated edition of ISO 19011: 2011 standard release
2015	Updated edition of ISO 9000:2015 and ISO 9001:2015 standard release

*composed by the authors [4; 5; 6]

There are four main changes:

1. Principles of quality management forming the basis of ISO 9001 standard requirements [7].

The previous version of the standard contained eight principles, now there are seven ones (Tab. 2).

Table 2

Comparative characteristic of quality management principles in ISO 9001:2009 and ISO 9001:2015* standards

ISO 9001:2009	ISO 9001:2015
1. Customer oriented	1. Customer oriented
2. Leadership	2. Leadership
3. Employee involvement	3. Staff involvement
4. Process approach	4. Process approach
5. System approach to management	
6. Continuous improvement	5. Improvement
7. Decision-making based on facts	6. Decision-making based on proof of facts
8. Mutually beneficial relationships with suppliers	7. Relationship management

* composed by the authors [4; 5; 6]

Such principles as customer orientation, leadership and process approach were left without changes.

The name change relates to these four points. At the same time the essential characteristics and contents did not have significant changes.

The principle of "system approach" disappeared as far as it is partially described in the "Process approach". However, the most significant reason for excluding this principle is that the implementation of the quality management system at the enterprise is already a systemic approach.

2. Standard structure. The change in the standard structure was caused by the fact that new version of ISO 9001 was developed in accordance with Annex SL - a new template for management system standards:

1. A single structure of the highest level of standards for management systems (ISO 14001, ISO 27001).

2. Identical text, general terms and definitions.

3. Improvement of coordination between various management systems.

4. Benefits for integration with other management systems.

Changes in the standard contents are given in Tab. 3

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Table 3

Comparative characteristics of ISO 9001:2009 and ISO 9001:2015* standards content

ISO 9001:2009	ISO 9001:2015
Introduction	
1. Scope of application	
2. Normative references	
3. Terms and definitions	
4. Quality management system	4. Organization environment
5. Management responsibility	5. Leadership
	6. Planning
6. Resource management	7. Control system maintaining
7. Products manufacturing	8. Manufacturing
8. Measurement, analysis, improvement	9. Effectiveness evaluation
	10. Improvement

* composed by the authors [4; 5; 6]

Terminology and definition of concepts have undergone the following changes:

1. New terms and concepts appeared.

An organization environment is a process that determines the factors that influence the purpose, purpose and sustainability of the organization. It takes into account internal factors including values, culture, knowledge and effectiveness of the organization. It also takes into account such external factors as legal, technological, competitive, market, cultural, social and economic environment.

Interested parties. The notion of interested parties extends beyond the scope of focus only on the customer. It is important to consider all relevant stakeholders.

Part of the understanding the organization environment process is identifying its stakeholders. Relevant stakeholders are those that have a significant risk of sustainability if their needs and expectations are not met. Organizations determine what results should be provided to these relevant stakeholders in order to reduce this risk.

Risk is the effect of uncertainty. Risk-oriented thinking is essential for the achievement of a successful quality management system. The concept of "risk-oriented thinking" was unclear in previous editions of this standard. For example, it covered the implementation of precautionary measures to eliminate potential inconsistencies, the analysis of any inconsistencies that appears and the adoption of measures to prevent their recurrence that are appropriate to inconsistency consequences [10; 8].

To ensure compliance with the requirements of this standard, the organization must plan and perform risk and opportunity reviews. Examining both risks and opportunities is the basis for improving the quality management system performance, achieving improved results and preventing negative impacts.

2. Some terms have been changed (Tab. 4).

Table 4

The main differences in terminology of ISO 9001:2009 and ISO 9001:2015* standards

ISO 9001:2009	ISO 9001:2015
Product	Products and services
Documentation, guidance on quality, documented techniques, protocols / records	Documented information
Working environment	The environment for the operation of processes
Means of monitoring and measuring equipment	Resources for monitoring and change
Procured products	Products and services received from outside
Provider	External Supplier

* composed by the authors [4; 5; 6]

3. Some terms are not used. The term "Exclusion". The organization must comply with all requirements of the standard. There cannot be any exceptions. However, when an organization defines the scope of the standard and if any of the requirements of the standard cannot be applied to this area, it

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can be excluded. In this case, the organization must thoroughly substantiate its action with the help of facts. However, most experts do not recommend doing this.

Some terms are not used. The term "Exclusion". The organization must comply with all requirements of the standard. There cannot be any exceptions. However, when an organization defines the scope of the standard, and if any of the requirements of the standard cannot be applied to this area, it can be excluded. In this case, the organization must thoroughly substantiate its action with the help of facts. However, most experts do not recommend doing this.

Also, such terms as "Representative of the leadership", "Preventive action", "Exceptions" disappeared from the standard.

ISO 9001 certificate for the quality management system does not guarantee the quality of the product or service provided. Designing and obtaining ISO 9001 certificate of serves is a kind of trust instrument. In simple words, this is a presentation of the company, which gives information about the manufacturer, about the organization of work in the enterprise, its compliance with the standards adopted in the modern business to the potential customer and consumer. ISO 9001 certificate is a document that shows the maturity of its management system.

Conclusions. The main differences between ISO 9001:2015 standard and its previous version are the construction of a quality management system and the setting of goals for it, taking into account external and internal factors unique to each organization (the context of the organization); compliance with the requirements of the quality management system of stakeholders; implementation of a risk-oriented approach to quality management system. ISO 9001 does not have the requirements to use official risk management in identifying risks and opportunities. An organization can choose the method that suits its needs; creation of mechanisms for the accumulation and updating intra-firm knowledge (knowledge management) as the basis for the development and improvement of organization and its processes; more emphasis are placed on managing changes in products, in the processes of organization and quality management systems in general.

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