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INTERNATIONAL STANDARD ISO 9001:2015 – ADAPTATION FOR FLEXIBILITY OF QUALITY MANAGEMENT

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МІЖНАРОДНИЙ СТАНДАРТ ISO 9001:2015 – АДАПТАЦІЯ ЗАДЛЯ ГНУЧКОСТІ СИСТЕМ УПРАВЛІННЯ ЯКІСТЮ ПІДПРИЄМСТВ

Purpose. Identification of the most significant changes in the new edition of international standards of quality management ISO 9001: 2015 concerning requirements to adaptability and flexibility of quality management at an enterprise.

Methodology. Key expectations from the implementation of international quality standards were estimated, and examples of some standards developing as alternatives to the standard ISO were provided. By comparing certain requirements fixed in various sections of ISO 9001: 2015, integrated links of four parts of this standard with flexibility and adaptability features of the quality management system (QMS) are given.

Findings. The development of international standards of quality management and their adaptation transformations according to the requirements of modern management at enterprises were studied. Examples of successful companies' transition to the construction of quality management systems based on alternative to ISO standards were found out. Such transitions are caused by certain conceptual shortcomings of international standards. The main changes in the updated quality standards ISO 9001: 2015 were analyzed which relate to changes in the orientation of standards on basic quality management methodologies. The effect of changes in standards on the formation of adaptability and flexibility of quality management systems as key elements to achieve the activity of organization efficiency on quality management was defined.

Originality. The scheme of requirements of the international quality standards to adaptability and flexibility of enterprise quality management systems was formed. The analytical model of connection between various sections of ISO 9001: 2015 regarding requirements to adaptability and flexibility of quality management systems was developed. These requirements form the framework for the development of quality management methods which can provide a certain level of flexibility of quality system at an enterprise.

Practical value. On the basis of formed schemes and models, management of the enterprise can determine separate components which can ensure adaptability and flexibility of the quality management system for developing its own quality management system.

Keywords: *quality management systems, flexibility and adaptability, international quality standards*

Introduction. The growth of interest in modern methods of quality management, high activity of international organizations who are developing standards for quality management systems, suggest the development of this area of management. Simultaneously with the development and emergence of novelties, many questions arise concerning the effectiveness and efficiency of modern methods of quality management systems improvement. These characteristics of systems form among others the requirement to flexibility and adaptability of management systems, flexibility of quality management methods in the context of the implementation and application of international quality standards. It is commonly known that there exists a certain process of transition from mechanisms of revealed shortcomings in available procedures of quality systems to the mecha-

nisms of these systems adaptability is known. That is, when signs of QMS flexibility level reduction appear, when available and used techniques do not provide appropriate flexibility in solving problems or support of the work on quality, the possibility of introducing or involving more flexible methods of quality management should be considered.

In other words, flexibility is formed and defined by using specific methods, while adaptability requires the change of those methods by other more flexible ones, depending on the situation, methods and techniques of quality management. This article is directed at the study of relationship between flexibility and adaptability of quality management systems and international standards of quality.

Analysis of the recent research and publications. The release of the official version of new ISO 9001: 2015 sparked a wave of publications with a variety of reflec-

tions, opinions and expectations. The changes proposed in the new version of the standard, which its authors formulate as the most important for the modern management system, consider a number of important components of the management of the organization. These changes are dictated by the large volume and depth of transformation that have occurred in management in recent years. The transformations caused by several key factors, both internal and external, to which organizations, their management systems can correspond only by the growing role of adaptability and flexibility of management. These features of management systems do not only provide a response to the change of organization's environment in the short term, but can provide its development over the long term.

Changes in the environment of global brands and companies encourage them, by adapting and gaining flexibility in management, to become more efficient in the context of energy efficiency, in the context of risk management, in context of applying the specialized experience, in the security context, etc. Therefore, the transition to new development vision of their own management and the development of companies has resulted, in particular, in neglecting the concept of key business processes because international standards concerning outsourcing suggest transferring even the most important phases and stages to specialized executors to create additional value. Thus, the constant adaptation does not leave any postulates which have been forming most of international standards for years. It would appear interesting from the methodological standpoint to analyze changes in international standards; the analysis enables one to notice or find key moments of changes which may create a new vision of the company by its own managers.

The emergence of ISO 14000 "Environmental Management" was caused by considerable public attention to environmental issues, especially due to the threat of the greenhouse effect, limitation of energy consumption, hazardous substances in household and industry, signing Kyoto and other environmental protocols at the level of governments of countries of the world, lack of drinking water, etc. [1]. With deepening environmental problems in the background, there emerged situations and needs of the economical use of fuel resources, which led to the publication of ISO 50001 "Energy management systems" [1].

Weight of influence factor and attention of society and public organizations to business activity and attention of business to social problems, problems of labor collectives led to the release of ISO 26000 "Guidance on social responsibility", ISO 31000 "Risk Management" and ISO 20121 "Event sustainability management systems", ISO 10002 "Quality management – Customer satisfaction – Guidelines for complaints handling in organizations", ISO 27001 "Information technology – Security techniques – Information security management systems – Requirements" and many others [1].

The release of ISO 37500 "Guidance on outsourcing" caused a lot of criticism, because it was about supporting the tendency in developed countries of transferring production processes into less developed countries with low wages and other cheaper resources. Critics of

these processes (processes which also obtained advanced tools of standardization) were even absolutely against such transfer of stages and phases of chains of creating additional value, including transferring abroad [2]. Critics of this practice and procedures provide data on the growth of unemployment in developed countries, in specific regions, and cities. They believe that unemployment is geographically linked to companies that order and practice outsourcing. As a result, enterprises or their structural subdivisions are closing and such processes should never be allowed, not to mention their standardization and promotion. However, deeper research into mass outsourcing in the USA proves the opposite direction of their influence. Low-tech production, that forms middle class consumers in these countries, is usually carried into less developed countries. Their welfare is growing as well as the demand for high-tech products manufactured in the United States where, in turn, employment increases.

Attention to the level of quality management, which should be preserved regardless of places of business processes, is an important reason and part of the standardization processes of outsourcing. There are numerous cases of quality audits by organizations which are responsible for issuing and verifying certificates of quality in companies with a large share of outsourcing. The task of auditors regarding issue or proof of compliance of the quality system at the enterprise with ISO standards is to check business processes. In some cases, it has become actually impossible because business processes take place in certain companies on the principle of outsourcing beyond parent organizational structures. In fact, there is no other way for the organization of ISO and its customers, seeking to fulfill the requirements of the standards, apart from standardization of certain stages of outsourcing process considering flexible management, and risks which are associated with this.

Unsolved aspects of the problem. Discussions of new standards including ISO, which can appear in the near future and have been released in the world, raise the question of their flexibility. Because of the variety of kinds and types of the standards, the question arises, which target group of companies they are directed at. The way how consumers' business requirements are changing and how standards follow those requirements step by step certainly indicates flexibility of the organization by itself. However, from the standpoint of enterprises, which form a certain package of requirements based on compliance with best practices and adapt management systems to them, the question of priority and expediency of such changes arises. These circumstances bring an important old question of key business processes, that are often difficult to find in modern company, territory or even impossible. It is impossible to find key business processes from the perspective of quality management system in a company which is a manufacturer, a final seller and a supplier of their products. For example, thousands of employees can be employed in the production while in sales there are a few tens of thousands. Production may require the constant attention of sellers to regular customers and willingness to deliver the product

in the short term. It is almost utopian to single out a key business process among production, sales or supply.

In addition, quality standards undergo constant adaptation and expansion in order to adapt to meet the needs of quality management systems in specific areas and countries considering the legislation, environment, security and others. Economy and efficiency which are achieved through the introduction of best practices, known business models also shape the demand for solutions which ISO offers [3].

Objectives of article. The objective of the article is to identify new directions of requirements for organizations' quality management systems in the context of requirements of adaptability and flexibility of quality management methods.

Presentation of the main research. In 2014–2015 biennium lively discussion was raised by the appearance of the project, and subsequently by the final version of ISO 9001: 2015. Experts analyze the new standard and point out a clear focus on support of adaptability and flexibility of quality management systems in companies. In particular, the following main reasons for the release of the new standard in the latest edition are distinguished [4]:

1. Significant changes in the world theory and practice of management, and in the business environment.
2. The emergence of new standards of quality management systems and strengthening of popularity of existing ones, which are alternative to ISO.
3. The recognition of certain requirements to quality management systems in ISO systems as outdated and lack of specific management tools that use other alternative standards.
4. Quality management system becomes an integrated feature in every subsystem of the company, but not a separate management function.

In recent years we have observed the development and interaction of three components of quality management sphere in management. Among them we include: 1) the characteristics of quality management systems, including such indicators as their adaptability and flexibility; 2) requirements for quality management systems from quality standards which tend to adaptability and flexibility; 3) characteristics and peculiarities of the development of international quality standards related to requirements to organizations from the environment on their flexibility and adaptability (Fig. 1).

The introduction of standards for quality management systems can reduce the adaptability and flexibility of quality management. Such cases are known in history and management departments of companies have an experience of finding a way out in developing their own standards in their business environment. So in 1988, the three largest car manufacturers in the US initiated the development of their own standards for quality systems on the grounds of low requirements of ISO standards. Requirements developed by them have been published and found the introduction and use in 1994–1997. The main motive of refusal from ISO standards at that time was low adaptability to the requirements of these standards to standards of automakers who were significantly dependent on suppliers and quality systems. This case in

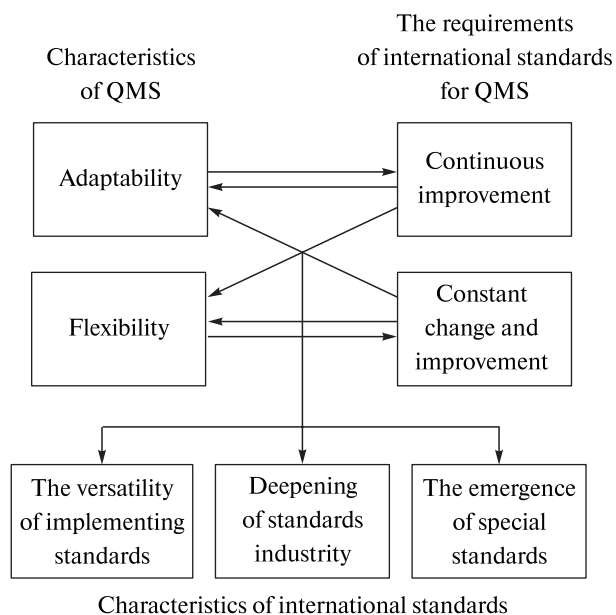


Fig. 1. The scheme of modern requirements for adaptability and flexibility of QMS from international standards

the history of quality management systems development is an example of how to choose an alternative to standards on the grounds of adaptability and flexibility.

Established notion about the motives and reasons for introducing standards of quality management systems or quality management is that they are a generally accepted mechanism for ensuring stability of work and development of quality management. This idea as well as standards has been steadily undergoing permanent criticism especially in recent years as the quality cannot be formed on the basis of stability or inviolability of statistics and rules. Quality can be considered a positive achievement at an enterprise or company if it is constantly improving, quality management system is improving, and quality indicators of company activities and production are increasing.

Critical moments in the ISO standards involve fairly high cost of certification and verification of certificates. The cost of certification of accredited companies, which form specific requirements to certain customers, conduct pre-certification, consulting, certification and confirming audits, depends on the number of employees in the company. There are examples of companies that voluntarily refused ISO certificates because their quality management system meets requirements that exceed the requirements of these standards or certification becomes not economically viable. The presence of certificate was not a criterion for a decision on cooperation with ISO neither for customers nor for partners or for suppliers of these companies. Moreover, it was expected that companies without ISO standard form a more competitive price for their products, which excludes additional articles of costing for certification. “Friweika eG” company (Germany) might be an example; after obtaining ISO-standards, the company preferred series of IFS Food standards (Version 5). This system is based on automation of management and production processes while quality management sys-

tem is based on the introduction of automated management systems of ERP or MRP2 type, which are more consistent with principles of adaptability and flexibility.

For companies with a diversified portfolio of fields of activities, or at deepening diversification, standards of quality management systems enable a flexible approach to quality management in different areas. However, flexibility of certain diversified units that correspond to different functional types of quality standards does not automatically mean flexibility of the entire organization. In large companies separate kinds of activities are often not self-sustaining or profitable. Support for such types of activities from the parent company can occur under the influence of other motives, for example, support of traditions and history of company activities, its image, etc. Interest in improving quality management systems of such units may decline significantly; parent companies do not foresee special measures to support the work of systems of quality in their budgets.

That is, efficiency and flexibility of the production system, as identical values actually, depend on innovative household system, their innovative potential. The main flexibility indicator, the level of flexibility, is considered to be an indicator that depends on the amount of time and various expenses required for carrying out certain changes, such as switching to manufacture of new products [5]. Costs are a part of such indicators as efficiency of household system performance and their flexibility.

It should be noted that there are certain standards for quality management systems that are completely aimed at achieving flexibility through a system of continuous evaluation and comparison. We mark the most aiming standard in the given direction – CAF (Common Assessment Framework) “general scheme of evaluation”. This system aims to create continuous monitoring of decision making accuracy in management of organizations with application of modern achievements in quality management systems (including standards ISO). This standard is especially useful for organizations of public nature and agencies of public administration because it provides constant interaction with interested community groups and certification or use of the standard is free for this sector.

Researchers of the sphere of public administration note that CAF system develops the idea of Balanced Scorecard, because it forms evaluation on the basis of objective data with consumers' estimates [6]. Basically, CAF models of quality management systems differ from standards of ISO 9001 series by the following features:

1) model of CAF system is focused on improving the quality at a certain achieved level, while ISO 9001 standards mostly require reduction of the probability of errors or inconsistencies;

2) ISO standards are more aimed at stable quality management system functioning through documentation and recording (to the editorial of 2015), CAF targets at a permanent evaluation and adjustment, speaking in terms of ISO;

3) using ISO, it is necessary to ensure the high flexibility of methods of the quality management system due to the fact that the standard often ignores the special and specific nuances and requirements of normative regula-

tion and legislation, while CAF determines and takes into account the constancy of changes implementation after being introduced in the company.

Evaluation of management practice in government agencies revealed that this is the Common Assessment Framework, CAF, which is more effective for public, municipal companies and public authorities [7].

While listing general shortcomings that were put forward by experts since 2000 to ISO systems, we can note that in their new version of 2015 many shortcomings were successfully removed, especially shortcomings and observations on adaptability and flexibility of quality management systems which meet ISO standards [8].

Let us provide a brief overview of those features of the new version, which suggest an increase attention to the adaptability and flexibility of quality management systems in ISO 9001: 2015 standards.

The newest edition of standards of ISO 9001: 2015 series does not focus, as their previous version of the ISO 9001: 2008 (PN-EN ISO 9001: 2009), on a system of documenting procedures in management system and recording all actions and protocols, but focuses on productivity and efficiency of organization. Productivity and efficiency include more detailed requirements for the procession approach and are based on the evaluation of risk of activity. Risk is evaluated according to new approaches with attention to the cycle of PDCA (PLAN-DO-CHECK-ACT) [9].

So, instead of 8 clauses of previous standard, we have 10 clauses in the new version, which describe procedural management issues of quality management system in more detail way. Generalization of previous 8 clauses had more formalized part of the issue of transitions among separate stages of the system, although they were considered in cyclical interpretation.

Apart from Clause 5.2 “Targeting the consumer”, which was included in the previous version of ISO 9001 and remained in the standard of new version, new Clause 4 “The environment of organization” was included. Clause 4.1 “Understanding the Organization and its context” predetermines building a model of company management which fully defined and monitored the environment and internal environment that can significantly affect the performance of the quality management system and the company in general. According to Clause 4.2 “Understanding the needs and expectations of interested parties”, companies are required to identify interested parties which can exercise influence on the quality management system, to determine the requirements of interested parties and carry out regular monitoring of their requirements. This can be described as some kind of disappearance of understanding of the enterprise environment as a static value. Instead, there appears understanding of the environment as a dynamic environment.

We should also mention the emergence of conceptually new clauses, including 6.1 “Actions to address risks and opportunities”. For ISO 9001: 2015, this feature means providing considerable weight to issues of effectiveness of the quality management system. First of all, the organization must determine their risks and opportunities which can affect activities of the organization

and its quality system. The range of organization tasks also include the formation of certain plans for responding to risks and opportunities.

Clause 6 “Planning” of the new ISO 9001: 2015 version contains in addition 6.3 “Planning of Changes”. This section forms the attitude to standards requirements of flexibility and adaptability of quality management systems. Because planning henceforth is not only subject to building or creating a quality system, but also its possible changes in the future. This section regulates the procedure for determining the need for changes in the quality management system and corresponding reaction of organization to implementation of these changes.

Clause 10 “Improvement” retained attention of quality management system to the principle of continuous improvement, in particular, in paragraph 10.2 “Nonconformity and Corrective Action”. In fact, these principles require the organization respond appropriately to occurrence of inconsistencies to certain corrective actions. In case of failure of corrective actions, the quality management system must be altered. In other words, the standard provides, among other things, possible changes in quality management methods used in companies.

Thus, if we analyze the relationship between certain adjusted Clauses in the new 2015 standard version, namely (Fig. 2):

1) Clause 4 “The environment of organization” (paragraphs 4.1 “Understanding the organization and its context” and 4.2. “Understanding the needs and expectations of interested parties”);

2) Clause 6 “Planning” (6.1 “Actions to address risks and opportunities” and 6.3 “Planning of Changes”);

3) Clause 10 “Improvement” (10.2 “Nonconformity and Corrective Action” and 10.3 “Continuous improvement”), we can say that there occurred a transition from the philosophy of preventive actions in the quality system to risk management and efficiency of the company. There was some kind of a shift from the standard of quality management to a standard of quality management governance [1, 10].

Peculiarities of new requirements in the standard, which are shown in Fig. 2, mean for organization paying more attention to efficiency, changes planning and assessment of effectiveness while implementing these changes. And it concerns both the organization’s quality as well as its management of the organization as a whole.

Conclusions and recommendations for further research. Major changes in updated standards of ISO 9001: 2015 affected primarily reorientation of standards as for core philosophies of quality management at enterprises. New components of this philosophy include commitment to management of efficiency, adaptability and flexibility. New standards form the philosophy of quality management on the basis of management changes (managing changes in organizations). First of all, the impacts of changes in the new version of standards form acknowledgment of flexibility and adaptability of quality management systems as key elements to achieve efficiency of organization of quality management.

Prospect for future research is to develop methods to achieve new standards requirements to enterprises in the

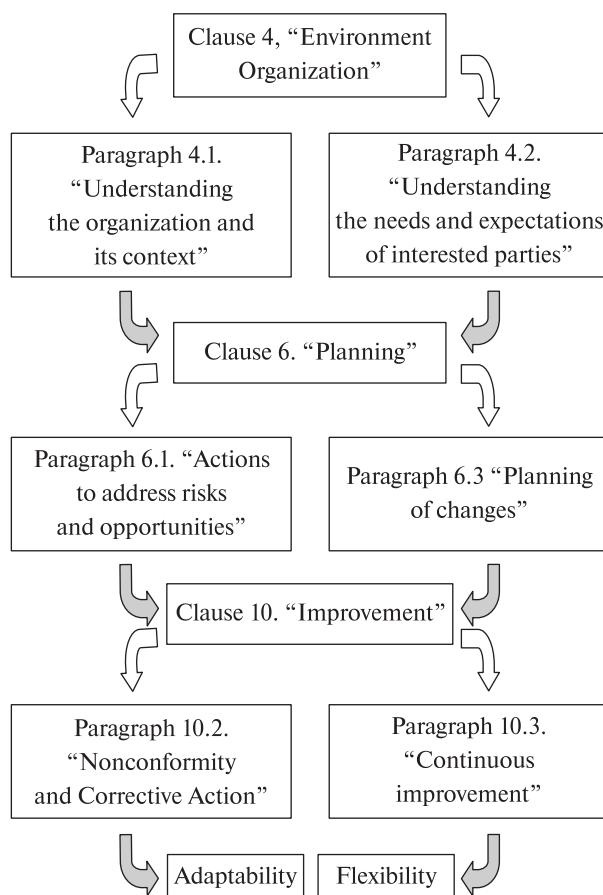


Fig. 2. Analytical model of links of certain Clauses in international standard ISO 9001: 2015 in the context of quality management system adaptability and flexibility support

sphere of quality. The requirements of quality standards to adaptability and flexibility of quality management systems of enterprises cannot be limited to the quality system since the model of connection between certain sections of ISO 9001: 2015 concerning the requirements to adaptability and flexibility extends beyond quality and covers a large part of company’s spheres of activities.

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Мета. Визначення найбільш значимих змін у новій редакції міжнародних стандартів систем управління якістю ISO 9001: 2015 стосовно вимог до адаптивності та гнучкості менеджменту якості на підприємстві.

Методика. Оцінені ключові очікування від впровадження міжнародних стандартів якості, наведені приклади розвитку окремих стандартів як альтернативних до стандартів ISO. Шляхом порівняння окремих вимог, зафіксованих у різних розділах ISO 9001: 2015, наведені інтегровані зв'язки чотирьох частин даного стандарту з характеристиками гнучкості та адаптивності системи управління якістю.

Результати. Вивчено розвиток міжнародних стандартів управління якістю та їх адаптаційні перетворення відповідно до вимог сучасного менеджменту на підприємствах. Виявлені приклади переходу успішних компаній до побудови систем управління якістю на базі альтернативних до ISO стандартів. Такі переходи зумовлені певними концептуальними недоліками міжнародних стандартів. Проаналізовані основні зміни в оновлених стандартах з якості ISO 9001: 2015, що стосуються зміни в орієнтації стандартів щодо основних методологій управління якістю. Визначено вплив змін у стандартах на становлення адаптивності та гнучкості систем менеджменту якості як ключових елементів досягнення ефективності діяльності організації з управління якістю.

Наукова новизна. Сформована схема вимог міжнародних стандартів якості до адаптивності та гнучкості систем управління якістю підприємств. Розроблена аналітична модель зв'язку між окремими розділами ISO 9001: 2015 щодо вимог до адаптивності та гнучкості систем управління якістю організації. Зазначені вимоги формують рамки для розвитку методів управління якістю, що можуть забезпечити певний рівень гнучкості системи якості на підприємстві.

Практична значимість. На підставі сформованих схем та моделей менеджмент підприємства може визначити для побудови власної системи менеджменту якості окремі складові, що можуть забезпечити адаптивність та гнучкість системи управління якістю.

Ключові слова: системи управління якістю, гнучкість та адаптивність, міжнародні стандарти якості

Цель. Определение наиболее значимых изменений в новой редакции международных стандартов систем управления качеством ISO 9001: 2015 в отношении требований к адаптивности и гибкости менеджмента качества на предприятии.

Методика. Оценены ключевые ожидания от внедрения международных стандартов качества, приведены примеры развития отдельных стандар-

тов как альтернативных стандартов ISO. Путем сравнения отдельных требований, зафиксированных в различных разделах ISO 9001: 2015, приведены интегрированные связи четырех частей данного стандарта с характеристиками гибкости и адаптивности системы управления качеством.

Результаты. Изучено развитие международных стандартов управления качеством и их адаптационные преобразования в соответствии с требованиями современного менеджмента на предприятиях. Выявлены примеры перехода успешных компаний к построению систем управления качеством на базе альтернативных ISO стандартов. Такие переходы обусловлены определенными концептуальными недостатками международных стандартов. Проанализированы основные изменения в обновленных стандартах качества ISO 9001: 2015, которые касаются изменения в ориентации стандартов основных методологий управления качеством. Определено влияние изменений в стандартах на становление адаптивности и гибкости систем менеджмента качества как ключевых элементов достижения эффективности организации по управлению качеством.

Научная новизна. Построена схема требований международных стандартов качества к адаптивности и гибкости систем управления качеством предприятий. Разработана аналитическая модель связи между отдельными разделами ISO 9001: 2015 в отношении требований к адаптивности и гибкости систем менеджмента качества организации. Указанные требования формируют рамки для развития методов управления качеством, которые могут обеспечить определенный уровень гибкости системы качества на предприятии.

Практическая значимость. На основании сформированных схем и моделей менеджмент предприятия может определить для построения собственной системы менеджмента качества отдельные составляющие, которые могут обеспечить адаптивность и гибкость системы управления качеством.

Ключевые слова: системы управления качеством, гибкость и адаптивность, международные стандарты качества

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ERGONOMIC PROVISION OF MODERNIZING MANAGEMENT PROCESSES OF METALLURGICAL PRODUCTION IN UKRAINE AND CHINA

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ЕРГОНОМІЧНЕ ЗАБЕЗПЕЧЕННЯ МОДЕРНІЗАЦІЇ ПРОЦЕСІВ УПРАВЛІННЯ МЕТАЛУРГІЙНИМ ВИРОБНИЦТВОМ В УМОВАХ УКРАЇНИ ТА КИТАЮ

Purpose. The creation of an ergonomic methodical approach to the modernization of management processes of metallurgical production, which involves a human factor while developing and exploiting the difficult man-machine system and estimating the degree of implementation of ergonomic requirements at different stages of an operator's activity planning.

Methodology. An analytical model of the organization of the research works devoted to the ergonomic modernization of man-machine systems was developed. Searching and purpose-oriented investigations at different stages of man-machine system development and exploitation were modelled from the sketchy projection till the exploitation of the system. Theoretical, system analytical and experimental methods were used.

Findings. The results of ergonomic modernization of management processes of metallurgical production in two countries under new economic (market) conditions were discussed. The factors, which define the tension in rolling-