THE DEVELOPMENT OF RISK-BASED THINKING PRINCIPLES AT A MACHINE-BUILDING ENTERPRISE UNDER CONDITIONS OF INDUSTRY 4.0

Yaroslav Vavilin
•
Bryansk State Technical University
vavilin@bk.ru

Abstract

The article deals with the problem of formal introduction of risk-based thinking features in machine-building production under conditions of Industry 4.0 together with the expansion of the use of digital technologies. The research aims to address the following objectives: to analyze the necessity and influence of risk management implementation within the organization's quality management system; to determine the levels required for realizing risk-based thinking; to develop a methodological foundation for integrating risk-based thinking considering Industry 4.0 elements; to perform a comparative analysis of the proposed model with known risk management systems. The study employs well-established methods of process-based approaches (Deming-Shewhart cycle) and systems analysis. The authors make an attempt to formalize the work on ensuring the proper use of risk and capability management tools from the perspective of a system analysis and process approach. Works related to risk management at the stages of the Deming-Shewhart cycle are highlighted and the levels and components of the machine-building production system model that are subject to analysis are determined. The task of introducing risk-based thinking in quality management systems of machine-building enterprises is critical due to the increasing complexity of products, increasing consumer demands and the need to ensure increased safety. Risk analysis makes it possible to identify potential threats to product quality in advance, minimize the consequences of defects, reduce error correction costs and increase the competitiveness of the enterprise in the market.

Keywords: quality, risk-based thinking, mechanical engineering, system, indicators

I. Introduction

A quality management system based on ISO 9000 series standards, version 2015, has got a risk and capability management as the main control component. The requirements for risk-based thinking is conditioned by the need of enterprise adaptation to rapidly changing environmental conditions and the transition to Industry 4.0 (field). Each structural arrangement has to identify and assess risks, as well as develop measures of minimizing or preventing them. The machine-building production system is a complex network of flow rate interrelation, heedful of the output quality where deep understanding and effective management are required particularly [1, 6 - 8].

In most cases the innovations (whichever is introduced: either technology or equipment, any management techniques) face two issues connected with economic efficiency and requirements by the law. According to the quality management concept any technology or technique within quality assurance framework, generating a profit (either by reducing process costs or by increasing demand), should be employed. Such quality management techniques and technologies (including risk-based thinking) can be attributed to the elementary units allowing continuous improvement, and over a long period of time (this approach is implemented in the philosophy of KAIZEN). Any marketing executive takes an interest in rapid growth and breakthrough technologies (KAIRYO), but such approach is typical for emerging economies and bears more risks.

The effectiveness of using quality management techniques and tools can be assessed in reducing potential costs when dealing with complaints and defects. Thus, they do not generate any obvious profits, and therefore, are provided financing residually. This results in formality for the technique application especially risk management. The choice comes down to using the simplest method of dealing with risks to meet the requirements of the standard and obtain a certificate. Under high competition and rapid changes, the key growth factor is the ability to anticipate (identify, analyze) and manage risk drivers and capabilities [9 – 18].

In this regard, it becomes necessary to form risk-based thinking, rather than the formal application of one or two of the simplest methods. It is good at all levels of structural arrangement management for operationalizing of the integrated implementation of risk management tools to identify threats timely and search for adaptability. Risk and capability management should become an integral part of the management decision-making process at all levels of the organization's management, from marketing research on product issues to strategic decisions on enterprise development. The introduction of integrated risk-based thinking as a subsystem of the overall management system, including quality management, at a machine-building enterprise will ensure sustainable development in an unstable economic situation and increase competitiveness not only due to the quality of products, but also hidden reserves of the organization.

The purpose of this work is to prepare a methodological framework for the implementation and development of a risk-based thinking system in a machine-building enterprise, as a quality management subsystem, aimed at identifying areas for the improvement.

II. Methods

To solve complex management tasks and implement the quality management principle of "evidence-based decision-making", it is advisable to use systems analysis methods that makes it possible to consider the company's activities as an integrated system, where all elements have an impact on the final result. This will help identify weaknesses and avoid the "process paradox", when the amount of funds allocated to improve the process is greater than the final result. A systematic approach to the organization's assessment and risk management will provide a comprehensive view of the corporate organization and facilitate informed decision-making [2 – 5]. The application of a systematic approach is fundamentally important for the comprehensive solution of product quality management problems. A systematic approach contributes to the formation of a holistic quality management strategy and optimization of business processes.

One of the key points of any management system is a process concept. A quality management system has been built on the process approach and the implementation of the Deming-Shuhart cycle (Plan-Do-Check-(Study)-Act), part of which is a risk-based approach, the effectiveness of which directly depends on a comprehensive solution to the task [20, 21]. The process approach is the most important prerequisite for effective product quality management and the functioning of modern organizations. This approach provides a structured representation of an enterprise's activities as a set of interrelated processes aimed at achieving its goals. The process structure promotes a clear division of responsibility between departments and improves employee coordination. Regular evaluation of the effectiveness of processes helps to make timely changes, adapt to changes in the external environment and maintain a high level of competitiveness of the organization.

III. Results

Seen as a whole from both systems theory and comprehensive approach point of view any organization (including a machine-building enterprise) can be described by a bunch of SFC elements:

$$S = \{M, P, P_r, T, W, C_i, C_o, O\}$$

where M – organization management, P –products, P_r -processes, T-applied technologies, W-employees (workers), C_i-internal relationships, C_o-external relationships, O - the outside environment of the organization. The final risk assessment of an organization can be calculated as a weighted mean value for each component.

Risk-based thinking components can be used at two levels of management: strategic – to assess financial risks and to mold possible strategies for the development of the enterprise on the one hand and on the other hand it is tactical, aimed at risks identification inherent in the output, personnel or technological support of the enterprise. At the same time, the choice of used methods will depend on the level of the organization's maturity and staff qualifications.

The decision to use the potential of risk-based thinking methods based on the ISO 31000 series standards should be built on the principles of a systematic approach (duality and integrity), that is, the boundary of the constituent elements, their mutual interrelations and the final result should be determined.

Any risk-based approach requires changes to the hierarchical set of values in the organization, namely:

1. Strategic level – outlining of the corporate management philosophy based on decision-making, considering a comprehensive analysis of risks and capability in regard to the process and product quality, technology control.

2. Tactical level – moving from the stage of a “fire- fighting” and solving problems in process of emergence, looking for the answer to a question "who is to blame?", to predicting and preventing potentially negative development of the situation (answering the question "how?").

3. Operational level – developing and implementing risk-based thinking system, in which each employee has a notion of why, how and for what the analysis is carried out.

Work can be divided into a cycle of five components:

1. Standardization. It includes activities related to the development of documented records procedure necessary for the roll-out process, conceptualization of the required work and reporting on them.

2. Automation. In the context of comprehensive digitalization and the transition to Industry 4.0, data collection and analysis should be carried out in conditions of minimizing the routine work of searching and analyzing information through the use of automated analytical systems and electronic document management.

3. Staff motivation. Providing training and systematization of knowledge in the field of quality management for employees at all levels of management and process performers.

4. Study of risk. Carrying out work on the identification, assessment and analysis of risk for each component of the organization's model, highlighting critical ones and developing corrective or preventive measures.

5. Management. Making decisions on the implementation of proposed corrective or preventive measures, as well as further development of the system.

As a basic system of continuous improvement, the works can be divided into stages in accordance with the Deming-Shewhart cycle (table). Depending on the organization's environment, the work cycle should be repeated with fixed cyclicity, but at least once a year.

Table 1: *Distribution of work by stages of the Deming- Shewhart cycle*

Stages	Complete activity
PLAN	Development and planning of work in the field of risk and capability management: 1. A preliminary analysis of the structural arrangement state, including self-assessment of processes improvement and staff qualifications of personnel (business services, operational staff and technical people). 2. Expert group formation for distribution of authority in procedures, taking into account the levels of their hierarchy and the task being solved. 3. Fixation of risk limits and scales for its assessment. If necessary, a rule for converting to a relative (point-rating) system is formulated in case of heterogeneous indicators ratio.
DO	Risk and capability assessment procedure: 1. The choice of risk management methods depends on the qualifications of the expert group and the complexity of the task being solved. 2. Information collection and its processing. 3. Formation of the final result.
CHECK	Comparing the obtained values with critical ones and making recommendations: 1. Comparison of the obtained values of the risk level with critical ones. 2. Analysis of the dynamics of the values of controlled risk parameters. 3. Development and approval of recommended corrective or preventive measures. 4. Development of a system of critical control points for monitoring risk factors.
ACT	Implementation of the proposed risk reduction measures: 1. Setting deadlines for implementation and designating job responsible persons. 2. Budget formation to eliminate (reduce) the level of critical risks. 3. Action tracking. 4. Review of criticality factors for the next reporting period.

Information technologies, being one of the key tools of modern management, can significantly improve any risk management efficiency. Since risk management becomes a part of the overall management of the organization, providing support for decision-making at all levels of the organizational structure, it must be integrated into the IT environment of the organization. CALS-technologies (Continuous Acquisition and Life cycle Support) provide continuous information support for deliveries and the whole product life cycle. They become the basis for collecting and analyzing information about the product and production, providing new horizons in quality, risk and capability management. A high degree of automation and control under processes allows identifying and controlling all potential risks, as well as ensuring data transparency and accuracy. The hierarchical model of using software product classes is shown in Fig. 1. Information flows form a closed cycle and ensure continuous improvement [19 – 21].

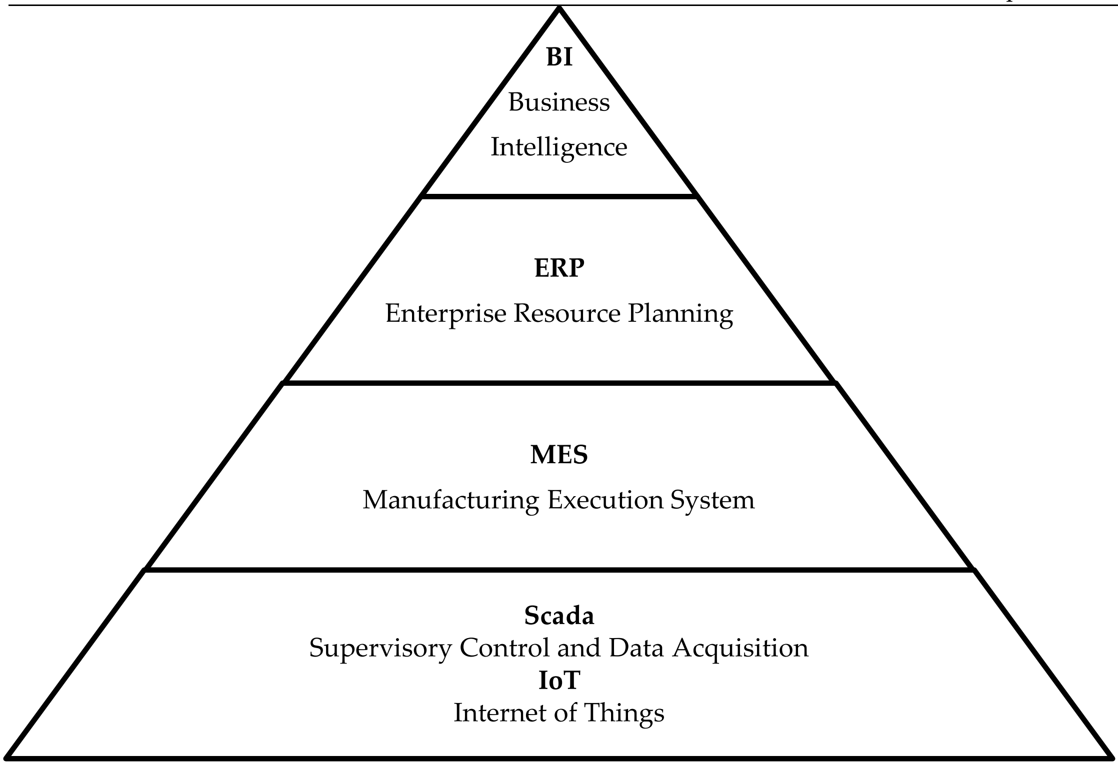

Figure 1: *Hierarchical model*

It is possible to identify a number of areas for the use of modern information technologies in the risk control field:

1. Automated data collection and processing with the use of specialized software complexes of the Scada and IoT class, making possible to get real-time information about the operation procedure. Such works become relevant from the earliest stages of forming a risk management culture –the stage of initial analysis.

2. Modeling opening scenarios, which allows predicting and modeling the probability of occurrence of events and their consequences, which contributes to making the right decisions in conditions of uncertainty. The growth of computing power and the ability to collect digital data allows building predictive models based on BigData analysis, which can be diagnostic for hidden patterns and trends.

3. Data analysis. The use of artificial intelligence (AI) and Big Data technologies makes it possible to ensure the widespread use of information from the knowledge bases (KBs) of an enterprise or group of enterprises, as well as to ensure the search for critically important information using linguistic variables.

No matter how perfect the technology is, much depends on people, who implement it. Therefore, personnel are the most valuable resource of any organization, especially at a machine-building enterprise. The creation of good causes and successful training system lays a solid foundation for the company's prosperity. Look at the Japanese experience, when one company becomes a place of work for several generations of employees. In the context of the transition to digital technologies and automation (robotization) of production, the task of adapting and creating "social" human-machine relationships arises ae well [15]. Digital technologies are just a supplement and are designed to facilitate routine tasks of personnel, such as collecting information regarding progress of execution or analyzing big data for making a management decision. The staff training and motivation system allows you to get an initiative employee who is interested in the best performance of the duties, and also forms the knowledge base of the enterprise.

IV. Discussion

The practical implementation of the information model can be different, built on the basis of a single information platform (for example, domestic developments of 1C or ModelRisk - a tool for analyzing risks in a spreadsheet for business, science, industry, and public administration), or using web portals (Figure 2).

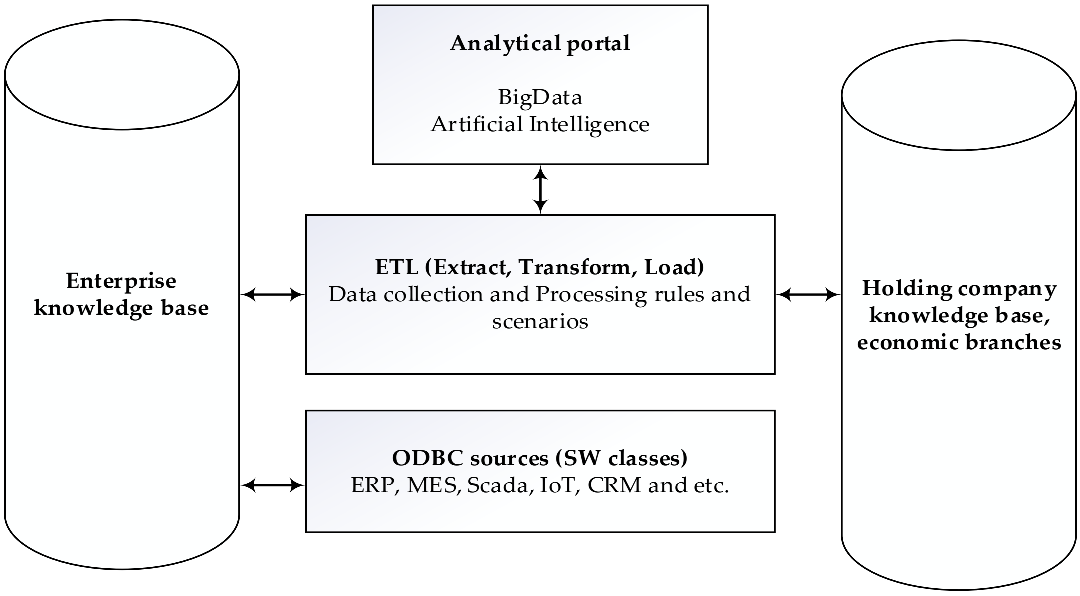

Figure 2: *Architecture of the analytical risk and capability management system*

One of the significant disadvantages of existing approaches in risk control field becomes the "isolation" within a single enterprise. Thus, there are situations when similar risks are eliminated in different ways within the same holding company and knowledge is not exchanged. This has a negative impact on resource conservation and prevents the use of the best available practices.

Generally, the work can be described by the following sequence of process implementation (information is exchanged using the organization's common knowledge base and cloud technologies): risk and capability management planning (Deming-Shuhart cycle Plan stage) using ERP systems (in particular, SAP Risk Management); implementation (Do- stage of the Deming-Shuhart cycle) – implementation of a risk assessment procedure based on data obtained from sources (Scada, IoT, CRM...) using AI, BigData technologies; presentation and analysis of the results obtained (Check stage of the Deming-Shuhart cycle) using AI, BigData, BI technologies; implementation of risk reduction measures (Act- stage of the Deming-Shuhart cycle).Considering the ratio of costs and benefits from the introduction of risk-based thinking (Figure 3), we can conclude that it is similar to the philosophy of KAIZEN – "playing the long game".

In the first part of the schedule (time period 1-3), costs increase sharply, which corresponds to the beginning of implementation work and is associated with the appearance of new expenses for training personnel, forming teams (cross-functional groups) for analysis, etc. Further (time period 3-7), the cost level decreases and stabilizes at a certain (minimum) level to maintain efficiency the process. There are no benefits at the initial stage (time period 1-2), which is quite logical, since data collection and analysis are being carried out and recommendations for improvement (improvement of activities) are being developed. Then (time period 2-3) there is a sharp increase – this is the area of correction of the first "critical" risks. In the following (time period 3-7), smooth growth is identified or revised risks control in a cyclically repeating analytical procedure. Such cycles will be repeated as the system develops and moves to a higher level of process improvement.

Figure 3: *Architecture of the analytical risk and capability management system*

The advantages of such a gradual approach include the "flexibility" of the model, which allows costs reduction in case of the wrong strategic decision making, as well as in conditions of significant influence from the outside environment of the organization, which in most cases is extremely difficult to predict.

Considering the elements of Industry 4.0, it is assumed that big data will be the most understandable for industry representatives and easy to implement elements for risk analysis. Consider the sequence of steps in building an analytical model for risk assessment:

Stage 1. Definition of Risk Analysis Objectives. This involves identifying key performance indicators (KPI), detecting risk factors, and establishing the goals of the analysis.

Stage 2. Data Collection and Preparation. Merely having access to large volumes of information is insufficient for obtaining high-quality results. An essential aspect is the correct formulation of the task for data collection. At this stage, linguistic artificial intelligence systems can be employed to automate the search and filtering of information based on key characteristics.

Stage 3. Risk Modeling. This entails applying statistical analysis methods, machine learning, and artificial neural networks to identify patterns and predict potential threats. The cost of risk mitigation increases with each new production transition; therefore, it is far more effective to prevent its occurrence than to address its consequences after detection. The use of mathematical tools in conjunction with computational machines enables the modeling of complex multivariate processes and provides adequate accuracy for predictive models.

Stage 4. Interpretation of Results and Development of Recommendations. Identified bottlenecks during the modeling phase should either be eliminated or subjected to a higher level of control.

As an example, consider the case "Analytical system for monitoring equipment operability". Equipment repairs are possible according to two components: 1) the standard operating time (this option is most often used) and 2) the actual condition of the equipment. An enterprise engaged in the transportation of hydrocarbons has implemented automated control systems for the condition of pumping equipment in a test mode and is deciding whether to put it into reserve or for maintenance based on its actual condition. The real-time performance characteristics of the equipment are captured using sensors (IoT) and transmitted for analysis. Depending on the characteristics obtained, a decision is made on the timing and scope of repairs. During the test mode, a 12% reduction in emergency situations related to equipment failure was revealed, and the period between routine repairs was increased by 7%.

V. Conclusion

Undoubtedly, there are various models of enterprise risk management. The approach proposed by the author to creating a risk analysis system is not the only one. The COSO Risk Cube is a three-dimensional model that visualizes the structure of an enterprise's risk management system (Enterprise Risk Management, ERM). Enterprise Risk Management-Integrating with Strategy and Performance clarifies the importance of enterprise risk management in strategic planning and embedding it throughout an organization-because risk influences and aligns strategy and performance across all departments and functions [22]. FERMA is a European standard for the organization of risk management, developed by the Federation of European Associations of Risk Management Specialists. The implementation of the FERMA risk management model takes place in seven stages: The formulation of the main goals and objectives of the enterprise. Risk analysis and assessment. Risk report. Decisions on the initial report. Risk management. Repeat report. Control [23, 24]. A comparison of popular risk management models is presented in the table 2.

Table 2: *A comparison of popular risk management models*

	COSO ERM	FARMA	ISO 31000	THE AUTHOR'S MODEL
Strengths	An integrated approach to risk management. Connection with strategic goals. Building the trust of stakeholders. Preparing for unexpected events.	A systematic approach. There are practical recommendations. Consideration of external and internal factors.	Versatility. Consideration of human and cultural factors. Continuous improvement.	Versatility. The use of advanced computer technology. Integration with the quality management system. Evidence-based decision-making. Emphasis on risk in the production process.
Weaknesses	The complexity of the structure. No step-by-step instructions. The need for adaptation.	Recommendation character. The need for adaptation. Some organizations may have difficulty implementing the FERMA risk management system due to the specifics of their business.	Inability to describe specific processes. The need for adaptation. Limitations of the methods described in the standard. There are no recommendations on the choice of methods	Lack of a standard. The need for adaptation.

Addressee — for whom the standard was created	The company's internal auditors	Professional risk managers	Any organization seeking to implement an integrated approach to risk management	Any organization seeking to implement an integrated approach to risk management
Required level of knowledge and skills of employees	High	Very high	Medium	Medium

The author made an attempt to present a variant of strategy in the formation of a risk-based thinking culture within a machine-building enterprise based on a system analysis and a process approach. At the same time, risk assessment should be carried out in different ways depending on the purpose and level of analysis (process, product, technology), and the overall integrated assessment is made through a weighted average of all estimates. The severity of each component is determined by the expert method. Not only the risks are identified, but also their impact on the entire organization. The system itself exists according to the principles of a process approach with continuous improvement based on the Deming-Shuhart cycle.

Experience proves that correction expenses during the transition from one stage of the life cycle to the next change significantly. This cost change is called the "tenfold cost rule", essentially it is much cheaper not to make a defect than to recover rejects. Despite almost a decade of a compulsory use of risk and capability management technique in various structural arrangements with various control levels, there are many "gray" areas due to management's lack of comprehensive insight into the problem or disinclination of the top management to implement such integrated approaches. Obtaining the coveted certificate of QMS compliance with ISO 9000 series standards does not guarantee that the system works as efficiently as possible. In mechanical engineering, as a key industry producing capital goods, there is great passivity and even resistance to innovations in the field of management. This is often associated with the concept of technological quality, i.e. ensuring quality through properly designed and selected technological processes, which, of course, is an important component of quality, but not the only one.

The meaningful effect of quality management tools implementation and the construction of an effective integrated management system based on a risk-based quality management with reference to the formation of Industry 4.0 in the country is a guarantee of industrial sovereignty of the state. A management culture based on a comprehensive assessment of the risks and capabilities of the organization (products, processes, technologies, management, etc.) based on the principles of process and system approaches simultaneously implements the principles of quality management and ensures the validity of strategic decisions. Either way, risks must be identified, assessed, and managed.

References

[1] Vasiliev Victor A. (2023) Information Technologies in the Organization of Production and Quality Management, Int. Conf. "Quality Management, Transport and Information Security, Information Technologies" (IT&QM&IS-2023), p. 3-8.

[2] Narusova Elena Yu., Struchalin Vladimir G., Paruleva Irina V (2023) Development of Hardware and Software to Ensure Process Safety and Reliability in Railway Transport, Int. Conf. "Quality Management, Transport and Information Security, Information Technologies" (IT&QM&IS-2023), pp. 59-63.

[3] Sukhanova Natalia V., Sheptunov Sergey A. (2023) The Neural Networks Application in Information Security, Int. Conf. "Quality Management, Transport and Information Security, Information Technologies" (IT&QM&IS-2023), pp. 74-78.

[4] WBCSD; COSO. Enterprise Risk Management Applying Enterprise Risk Management to Environmental, Social and Governance-Related Risks. 2018. Available online: https://docs.wbcsd.org/2018/10/COSO_WBCSD_ESGERM_Guidance.pdf (accessed on 4 May 2025).

[5] Hanmei Wu, Xiaoqing Cai, and Man Feng, Risk management of engineering projects installation using Analytic Hierarchy Process Infrastructure Asset Management 2025 12:1, 57-69

[6] International Organization for Standardization. Guidance on: Auditing Climate Change Issues in ISO 9001; International Organization for Standardization: Geneva, Switzerland, 2024.

[7] WEF. World Economic Forum, The Global Risks Report; WEF: Geneva, Switzerland, 2024; Available online: https://www3.weforum.org/docs/WEF_The_Global_Risks_Report_2024.pdf (accessed on 4 May 2025).

[8] ISO 9001:2015 Quality Management Systems – Requirements. International Organization for Standardization: Geneva, Switzerland, 2015.

[9] Joshi, Satyadhar, Leveraging Prompt Engineering to Enhance Financial Market Integrity and Risk Management (January 15, 2025). World Journal of Advanced Research and Reviews, 2025, 25(01), 1775-1785 DOI: 10.30574/wjarr.2025.25.1.0279

[10] Yazo-Cabuya, E.J.; Ibeas, A.; Rey-Caballero, R. Multi-Criteria Decision Making for Risk Management in Quality Management Systems. Sustainability 2025, 17, 1092. https://doi.org/10.3390/su17031092

[11] Dong, T., Li, H. & Zhang, Z. The using effect of fuzzy analytic hierarchy process in project engineering risk management. Neural Comput & Applic 37, 7935–7945 (2025). https://doi.org/10.1007/s00521-023-09046-2

[12] Jiang, S.; Cao, X. Rule Inferring for Engineering Quality Risk Management Based on Ontology in Housing Construction. Sustainability 2025, 17, 1643. https://doi.org/10.3390/su17041643

[13] N. Banaitiene and A. Banaitis, Risk Management in Construction Projects, Risk Management - Current Issues and Challenges. InTech, Sep. 12, 2012. doi: 10.5772/51460.

[14] Zhang, F.; Yang, Y.H. Feature Vector Extraction Algorithm Based on Big Data in Engineering Quality. Engineering 2021, 257, 02029

[15] Faheem M, Shah SBH, Butt RA et al (2018) Smart grid communication and information technologies in the perspective of Industry 4.0: opportunities and challenges. Comput Sci Rev 30:1–30

[16] L.J. Basile, N. Carbonara, U. Panniello, R. Pellegrino, The role of big data analytics in improving the quality of healthcare services in the Italian context: The mediating role of risk management, Technovation, Volume 133, 2024, 103010, ISSN 0166-4972, https://doi.org/10.1016/j.technovation.2024.103010.

[17] Bazaluk, O., Pavlychenko, A., Yavorska, O. et al. Improving the risk management process in quality management systems of higher education. Sci Rep 14, 3977 (2024). https://doi.org/10.1038/s41598-024-53455-9

[18] Marilyn F. Braine, Matthew Kearnes, Stuart J. Khan, Quality and risk management frameworks for biosolids: An assessment of current international practice, Science of The Total Environment, Volume 915, 2024, 169953, ISSN 0048-9697, https://doi.org/10.1016/j.scitotenv.2024.169953.

[19] Szelągowski, Marek, Justyna Berniak-Woźny, and Magdalena Wójcik-Jurkiewicz. Redefining The Deming Cycle for Industry 4.0/5.0. Zeszyty Naukowe Akademii Górnośląskiej 9 (2023): 223-235.

[20] Trippner-Hrabi, Justyna, Jacek Chądzyński, and Aygun Kam. Unveiling the Significance of the PDCA Deming Cycle. Ethics and Innovation in Public Administration 299 (2024).

[21] Ten, Chee-Wooi, and Yunhe Hou. Modern power system analysis. CRC Press, 2024. [1] Figueredo, A. J. and Wolf, P. S. A. (2009). Assortative pairing and life history strategy - a cross-cultural study. *Human Nature*, 20:317–330.

[22] The Committee of Sponsoring Organizations (COSO) https://www.coso.org/ accessed on 24 May 2025).

[23] Risk management standards https://www.gd.ru/articles/12547-standarty-upravleniya-riskami (accessed on 4 May 2025).

[24] Strelnik M.M. Comparison of risk management standards (COSO ERM, FERMA and ISO 31000:2009) // Proceedings of St. Petersburg State University of Economics. 2014. No. 7. pp. 116-119.