

**THE EFFECTIVENESS OF THE INTEGRATED MANAGEMENT SYSTEM,
BASED ON THE RISK-BASED APPLICATION OF THE REQUIREMENTS
INTERNATIONAL STANDARD ISO-9001: 2015.**

Adil Ali Gasimov*, Director of the Quality Assurance Centre,
Western Caspian University, Baku, Azerbaijan

* ORCID 0000-0003-3694-5543

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*Стаття отримана редакцією 18.05.2021 р.
The article received by the reduction 18.05.2021.*

Introduction. Today, when the whole world is faced with external risks (COVID-19 pandemic, inflation, economic crisis, etc.) that dictate the conditions in the health market for us, the topic of applying the risk management system is becoming more relevant and demand. Faced with the manifestation of negative consequences of external risks, there is a threat of an increase in internal (both at the level of potential and at the level of possible) risks in the activities of the organization.

Nowadays, both representatives of large business communities and corporations and representatives of small businesses are unanimously in solidarity in the application of risk management methods at the production level, which is the key to the success of strategic competitiveness. The introduction of a risk management system into the practice of any organization makes it possible to ensure the stability of their development, increase the validity of decision-making in risky situations, and improve the financial situation by carrying out all types of activities under controlled conditions.








Results. Risk-based thinking is a mechanism for managing the planning and implementation of measures and methods used by an organization to manage and control risks that affect its ability to achieve planned goals. The concept of risk management was traced in the 9001 version of the standard, representing the requirements for preventive action. In the version of the ISO 9001-2015 standard, the term "risk-based thinking" appears. Risk (according to ISO 9001:2015) is the effect of uncertainty on the result of any activity, in the form of a negative deviation from the expected result. Risk is present in the activities of organizations of any type. However, they are different for each organization. All risk factors at the enterprise can be subdivided, depending on the area of occurrence, into external and internal. The principles necessary for effective implementation of risk management are established in the 5th publication of the International Standard ISO-9001:2015 "Quality Management System". A system based on the ISO-9001 requirements model, as a rule, is defined in the format of a strategic goal and direction of senior management to reduce the level of risks of work processes (potential risks) or to prevent and suppress them at the root (potential). Risk analysis statistics in various organizations show that operational risks are potential threats arising from inadequate or unclear organizational processes or deviations from established norms and requirements that arise in work processes due to human error or system errors. At the same time, the influence of external events that negatively affect the activities of the organization is very important. Hence, we can conclude that operational risk management and the process approach to quality management have a lot in common.

Any risk can be characterized by 4 main factors (table 1).

Risk management implies the creation of the necessary culture and business infrastructure for:

- identifying the causes and main factors of the occurrence of risks;
- identification, analysis and assessment of risks;
- making decisions based on the assessment made;
- development of anti-risk control actions;
- reducing the risk to an acceptable level;
- organizing the implementation of the planned program;
- monitoring the implementation of planned actions;
- analysis and evaluation of the results of a risk decision.

Table 1

Main risk factors				
Negative factor		Will happen	Will not happen	Consequences
1.	Event or incident			There is a certain threat of negative impact on the activities of the organization.
2.	Certain risk			Uncertainty
3.	Unambiguous occurrence of risk			There are certain negative consequences for work processes.
4.	Vulnerable point of the organization's activities (or "weak point")			Significant negative consequences that entailed financial, production, resource, reputation and other damage.

Considering the above-mentioned signs and criteria of the risk management mechanism, it should be noted that the need to develop a nonconformity management system and a mechanism for determining corrective actions is a significant factor influencing effective risk management / coordination. This process can be the main source of information about the possible and potential risks that the organization may face in its activities. The use of an integrated mechanism for risk coordination and management of corrective actions will allow you to control the trends of reducing or avoiding risks in the daily activities of work processes.

According to the requirements of clause 10.2 of ISO-9001:2015 “in the event of inconsistencies”, including those related to claims, the organization must determine the methods of response to the identified inconsistency and a mechanism for assessing the necessary actions to determine and eliminate the causes of the inconsistency. This process avoids the recurrence of these kinds of problems. At the same time, the standard clearly defines step-by-step requirements for dealing with existing problems. In particular, the organization should:

- 1) analyze the revealed discrepancy;
- 2) determine the reasons that caused the emergence of nonconformity;
- 3) determine the presence of an identical deviation from the norm of nonconformity or the possibility of its occurrence in other work processes of the organization;
- 4) take all necessary actions in relation to the elimination of the nonconformity;
- 5) analyze the effectiveness of each corrective action taken;
- 6) update, if necessary, the risks and opportunities identified during planning;
- 7) make, if necessary, changes to the quality management system.

A significant factor in the effectiveness of this mechanism is the documentation and maintenance of relevant information databases.

It should be noted that the main goal of corrective actions is aimed at eliminating the causes of nonconformities in order to prevent their recurrence. A detailed analysis of the problem should be aimed at determining the cause of its occurrence. As a rule, in this phase it is desirable to apply the “Ishikawa diagram”, “Five why” or “Paretto” methods. After that, it is very important to determine a plan of corrective actions aimed at eradicating the causes (determining the timing of their implementation and responsible persons).

At the level of centralized management of the management system, it is important to define a mechanism for managing actions in relation to the coordination of potential and possible risks, which acts as a guarantee that, through the means of work processes, the organization is able to achieve its objectives and intended results. It is very important to focus on the methodology for assessing industrial risks. Most organizations use the “Probability and Risk Rating” methodology (5x5 format with color grades) as in table.

For a more effective functioning of the integrated mechanism for dealing with nonconformities and coordinating risks in the organization, a monitoring procedure should be determined (reflecting all the basic principles and a description of the process of conducting internal and external audits and other monitoring methods). Due to the main monitoring goal set for the Quality Control Service – to assess the actual state of work processes, it is possible to identify realized/potential and determine possible risks. Consequently, the applied quality assurance system based on the principles of ISO-9001:2015 requires the use of "preventive actions" aimed at mitigating the possible and potential consequences of identified risks, which is presented in today's light as the concept of "Risk Management". It is for this reason, in connection with the development of the "risk assessment" methodology that the additions made to clause 6.1. “Actions to address risks and

opportunities” ISO-9001:2015 completely eliminated the requirements for “Preventive action” (8.5.3. “Preventive action”) as a separate process and defined it as the main component of the fifth publication of the ISO-9001 Standard.

Table 2

Rating of likelihood and risk						
Probability (A) that this can happen	This will happen (in the near future) “5 points” <i>Very likely (>90%)</i>	5	10	15	20	25
	Most likely it can happen “4 points” <i>Probably (>65%)</i>	4	8	12	16	20
	This can happen in exceptional cases “3 points” <i>“50 50” (35% - 65%)</i>	3	6	9	12	15
	It can happen, but on rare occasions “2 points” <i>Unlikely (<35%)</i>	2	4	6	8	10
	It is highly unlikely that this will happen “1 point” <i>(<10%)</i>	1	2	3	4	5
Level (B) <i>Probability (A) x Impact (B) = Overall Risk Score</i>	Minor “1”	Middle “2”	Significant “3”	High “4”	Critical “5”	

By defining the sequence and interaction of the above-mentioned processes, it is possible to schematically display a typical mechanism for the operability of mechanisms for managing nonconformities, coordinating production risks and the procedure for conducting internal audits, displayed in a single form of centralized management of corporate management (fig.1).

It should be noted that the use of an integrated mechanism for managing nonconformities and coordinating risks creates effective conditions for identifying latent deviations from the established rules by the organization itself or the requirements of legislative and international norms.

Conclusions. Analyzing data on frequently occurring production risks or frequently occurring inconsistencies, it can be noted that the prevention of risks or most of them are mitigated by the introduction of QMS processes (their level is reduced or the possibility of their prevention is provided), based on the requirements of the International Standard in the field of quality management system.

Potentially effective benefits from the application of a Quality Management System based on the principles and requirements of ISO-9001:2015:

- the organization's ability to consistently provide quality services or products at a high level;
- effective opportunities to increase the level of customer satisfaction;
- effective work on the management and coordination of production risks and organizational capabilities;
- maximum compliance with the established requirements of the corporate governance system.

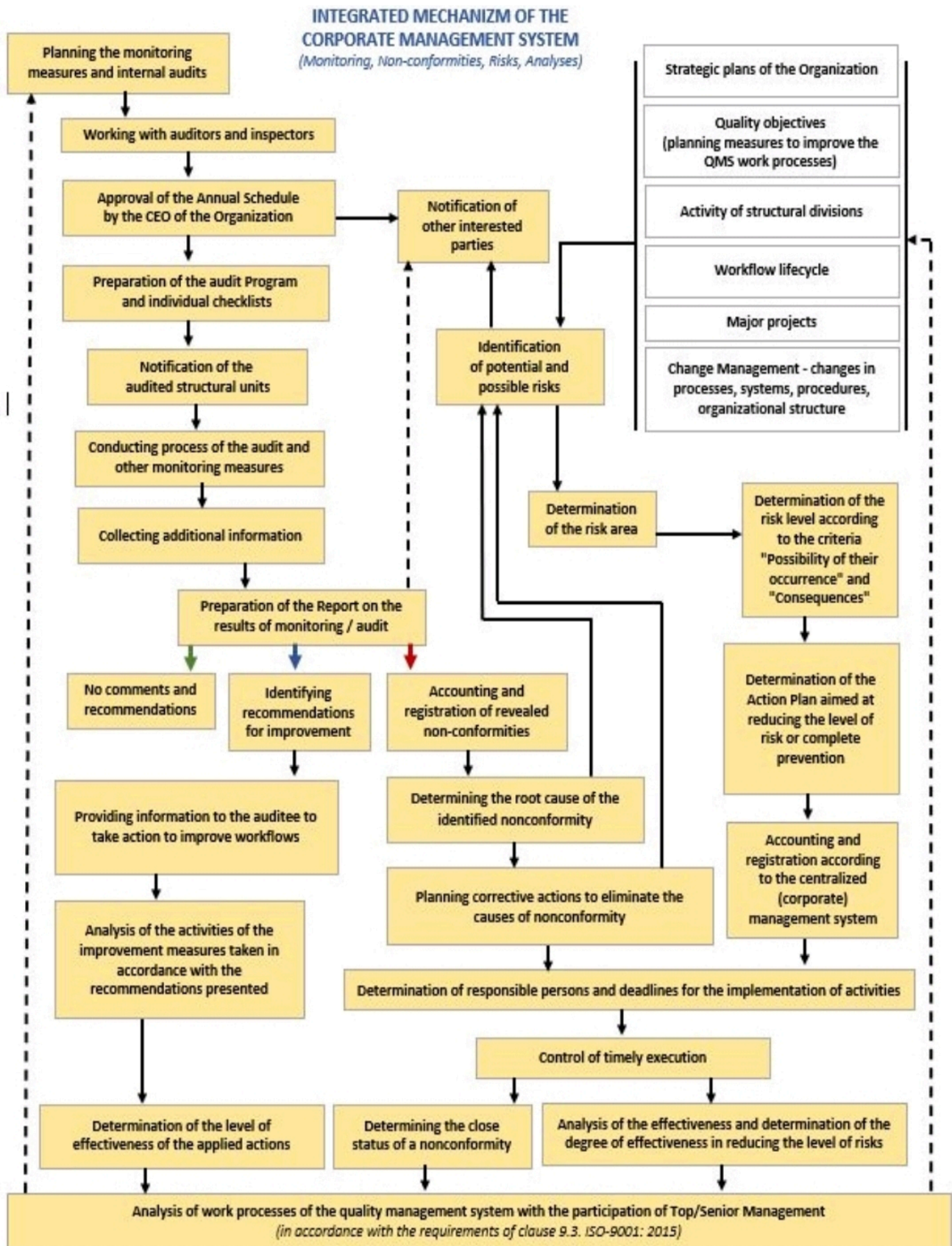


Fig. 1. Integrated mechanism of the corporate management system

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УДК 338.2

JEL 039

Адїл Алі Гасїмов, директор Центру забезпечення якості. Західно-Каспійський університет, Баку, Азербайджан. **Ефективність інтегрованої системи управління на основі ризиків, заснованої на застосуванні вимог міжнародного стандарту ISO-9001: 2015**. Розглянуто роль інтеграційних процесів системи управління якістю у галузі цивільної авіації. Ураховано й обґрунтовано процес ефективної імплементації IMS у корпоративному середовищі. Проведено аналіз документа ICAO-9859 та обґрунтовано необхідність упровадження інтегрованої системи корпоративного управління в організаціях, що працюють у цивільній авіації. Доведено переваги використання інтегрованих систем. Висвітлено загальні й конкретні принципи системи управління безпекою (SMS) та системи управління якістю (СМК). Створену систему для ефективної імплементації IMS розглянуто на конкретному прикладі застосування вимог Посібника з управління безпекою.

Ключові слова: інтегрована система управління (IMS), система управління безпекою (SMS), система управління якістю (СМК), ICAO, IATA, управління дотриманням вимог, якість, безпека.

UDC 338.2

JEL 039

Adil Ali Gasimov, Director of the Quality Assurance Centre, Western Caspian University, Baku, Azerbaijan. **The Effectiveness of the Integrated Management System, Based on the Risk-based Application of the Requirements International Standard ISO-9001: 2015**. The article considers the role of integration processes of the quality management system in the field of civil aviation. The process of effective implementation of IMS in the corporate environment is taken into consideration and substantiated. The analysis of ICAO-9859 Document is carried out and the need for the implementation of an integrated corporate management system in organizations operating in civil aviation is described. The advantages of using integrated systems are distinguished. General and specific principles of the Safety Management System (SMS) and Quality Management System (QMS) are highlighted. The created system for the effective implementation of the IMS is considered using a specific example of applying the requirements of the "Safety Management Manual".

Keywords: Integrated Management System (IMS), Safety Management System (SMS), Quality Management System (QMS), ICAO, IATA, Compliance Management, Quality, Safety.