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INTEGRATING THE RISK MANAGEMENT PROCESS INTO THE QUALITY MANAGEMENT SYSTEM OF THE TESTING LABORATORY

ИНТЕГРИРОВАНИЕ ПРОЦЕССА УПРАВЛЕНИЯ РИСКАМИ В СИСТЕМУ МЕНЕДЖМЕНТА КАЧЕСТВА ИСПЫТАТЕЛЬНОЙ ЛАБОРАТОРИИ

Savitsky K., Makhon A., Karpushenko I.^a

Vitebsk State Technological University, Republic of Belarus

E-mail: ^akarinstep@rambler.ru

Савицкий К. Г., Махонь А. Н., Карпушенко И. С.^a

Витебский государственный технологический университет, Республика Беларусь

ABSTRACT

*RISK, RISK-MANAGEMENT
PRINCIPLES, QUALITY MANAGEMENT
SYSTEM, TESTING LABORATORY,
ACCREDITATION OF LABORATORIES*

The article presents data on structural changes in the new version of GOST ISO / IEC 17025-2019 and the results of adapting the principles of risk management to the main activities of the testing laboratory.

АННОТАЦИЯ

*РИСК, ПРИНЦИПЫ УПРАВЛЕНИЯ
РИСКАМИ, СИСТЕМА МЕНЕДЖМЕНТА
КАЧЕСТВА, ИСПЫТАТЕЛЬНАЯ ЛАБОРА-
ТОРИЯ, АККРЕДИТАЦИЯ ЛАБОРАТОРИИ*

В статье представлены данные о структурных изменениях в новой версии ГОСТ ISO/IEC 17025-2019 и результаты адаптации принципов риск-менеджмента к основной деятельности испытательной лаборатории.

In the process of accreditation of a testing laboratory, it is necessary to update the quality policy in accordance with the requirements of GOST ISO/IEC 17025-2019, as well as to include risk management in the list of strategic goals in the field of test quality.

The laboratory's risk-management policy may include:

- statement of the laboratory management's focus on risk management in relation to the stated goals;
- the intention to implement risk-management in the practice of making any

decisions, performing any actions and processes;

- defining the authority, responsibility, and accountability of staff;
- the obligation to ensure access to the necessary resources for those responsible for risk management;
- commitment to involve as many stakeholders as possible in risk management;
- establishing risk-management performance indicators;
- allocation of resources for risk management;
- ways to resolve conflicts;
- the obligation to review and improve the risk-management policy and structure periodically, as well as in the event of changes in circumstances;
- striving to improve risk-management.

ISO 31000:2018 helps to integrate the risk management process into the overall management scheme of the testing laboratory, processes, policies and culture of the organization, which contains principles and General guidelines for effective identification and risk management.

Table 1 shows the result of adopting the principles of risk management to the laboratory activities of the testing laboratory.

Table 1 – Principles of risk-management for testing laboratories

Principle	Content	Application for testing laboratories
1	2	3
Integration	Risk-management is an integral part of the organization's activities and contributes to its improvement	Risk-management is part of the testing laboratory's management system (GOST ISO/IEC 17025-2019)
Universality	Risk management is an integral part of all the management processes of the testing laboratory	Risk management is part of management's responsibilities. Any management decision is made based on a risk analysis. The testing laboratory uses risk management on a planned and event-based basis
Adaptedness	The structure and process of risk management are correlated and adjusted to the external and internal context of the organization	Risk management must correspond to the external and internal context. ISO/ IEC 17025:2017 establishes mandatory risk-management only for laboratory activities (the laboratory has the right to apply this approach in other areas as well)

End of table 1

1	2	3
Inclusiveness	Appropriate and timely involvement of stakeholders allows us to take into account their knowledge, views and opinions.	Risk management is transparent and takes into account the interests of different parties. The main stakeholders are the laboratory's specialists and its clients
Dynamism	Risks may arise, change, or disappear as the external and internal context of the organization changes. Risk management forecasts, detects and responds to these changes and events in a timely and appropriate manner	Any change in the context should entail a risk analysis. Identified risks should be regularly reviewed to ensure effective and reliable results
Consideration of human and cultural factors	Human behavior and culture significantly affect all aspects of risk management at every level and stage	The main source of inconsistencies in the testing laboratory is the human factor. The laboratory must necessarily take it into account when analyzing risks and identifying their sources
Continuous improvement	Risk management is constantly improved through training and experience accumulation	Risk management contributes to the continuous improvement of the organization, since the organization must develop a strategy for improving risk management along with improving other aspects of its activities

"Impartiality" and "Confidentiality" requirements play an essential role in integrating risk management processes into laboratory activities (Fig. 1).

For practical implementation of Section 4.1 "Impartiality", it is recommended to keep records in the following order:

- analysis of potential risks of impartiality, including risks related to the laboratory's activities, its relationships, and relationships within its staff;
- measures to eliminate or minimize risks associated with impartiality;
- action plan: develop and implement appropriate actions.

In order to implement section 4.2 "Confidentiality" in the activities of the testing laboratory, the client must be notified in writing that the laboratory intends to publish the data in open sources. The notification must be provided prior to

the start of laboratory testing and should therefore be included in the contract or other similar document. Information about customer data remains confidential. Laboratory employees and service providers must also sign a declaration of confidentiality.

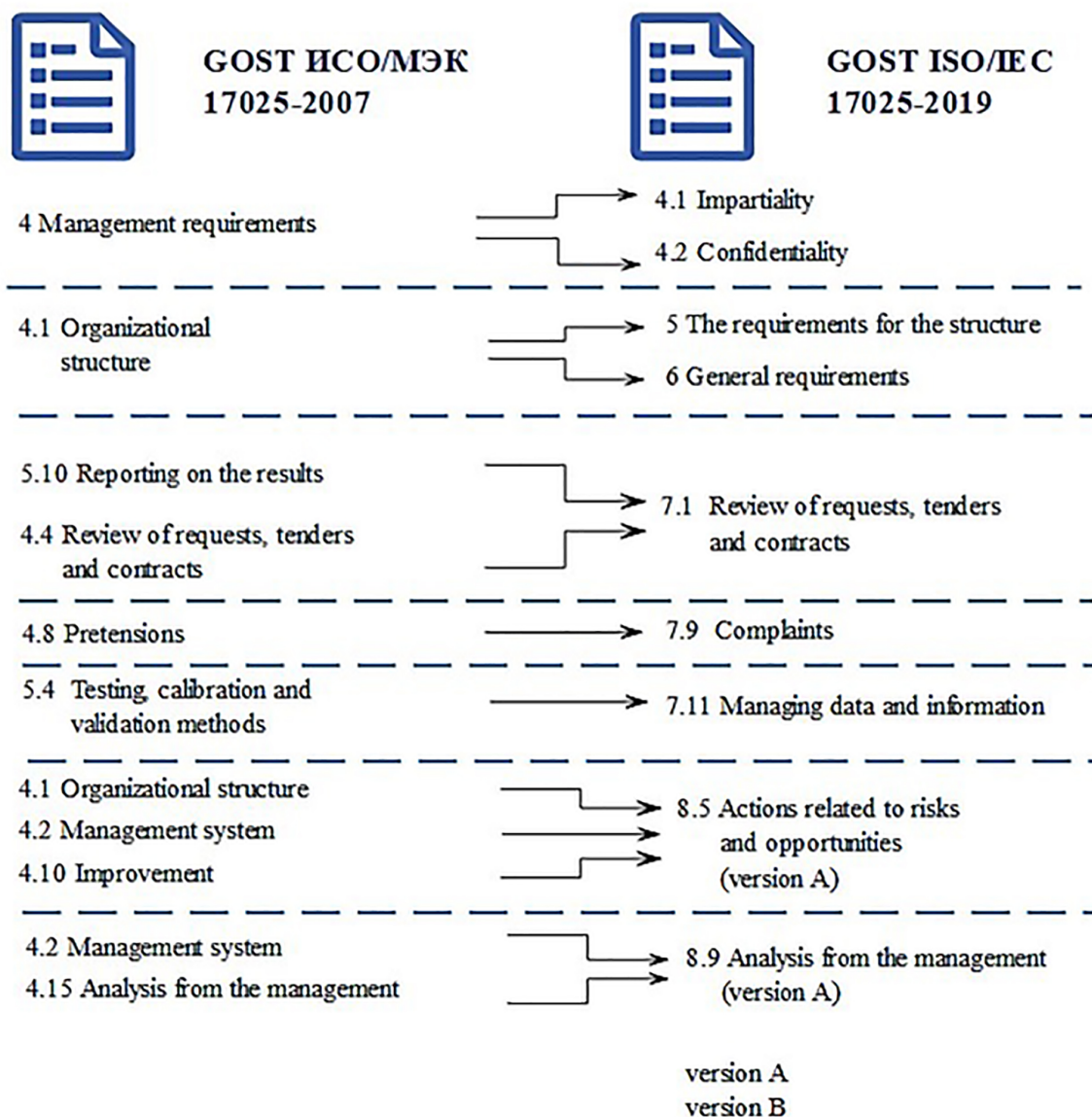


Figure 1 – Scheme of structural changes in GOST ISO/IEC 17025-2019

Integration of risk management in a testing laboratory begins with the analysis of external and internal factors that can influence the success of the laboratory in achieving its goals. The testing laboratory is characterized by consideration of risks in the field of accreditation, preservation of state and commercial secrets, handling of toxic and radioactive substances, ensuring industrial, fire, environmental, and

sanitary safety. The internal context is also considered in the same way. Description of the context, it is recommended to document each year.

References

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