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Improving the Quality System through Systematizing the Risk Management Process in Analytical Testing Laboratories

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Abstract: The accuracy, reliability and compliance of activities in modern analytical testing laboratories directly depend on an effectively functioning quality system. The quality management system (QMS) serves not only as a means of documenting and managing results in the laboratory, but also as the main infrastructure ensuring the stability of processes. Therefore, international standards such as ISO/IEC 17025:2017 and ISO 9001:2015 impose strict requirements on the laboratory quality system. In particular, requirements such as continuous quality improvement, risk-based thinking, documented information management, internal audits and elimination of undetected nonconformities have become an integral part of laboratory activities.

This article analyzes improved risk management methods in testing laboratories, their digitalization, and the process of integrating them into the quality management system.

Keywords: testing laboratory, risk management, risk identification, risk analysis, quality management system, systematization.

Introduction

A quality management system is a set of systematic controls and processes necessary to implement an organization's quality policy and objectives. The ISO 9001:2015 standard places the principles of a "process approach" and "risk-based thinking" at the heart of a quality management system. It is these principles that require the early identification, assessment and effective management of risks that may arise in laboratory activities [1].

Similarly, the international standard ISO/IEC 17025:2017 also defines the reduction of quality by identifying and managing risks as a fundamental requirement, in addition to the technical capacity of the laboratory. Clause 8.5.1 of this standard states that the organization must "plan actions to identify and prevent potential nonconformities", and clause 8.5.2 states that the results of these actions must be monitored, documented and continually improved. This, in fact, requires the inclusion of the risk management process in the QMS [2].

However, the risks encountered in laboratory activities are diverse: improper testing, unqualified personnel, equipment malfunctions, outdated or outdated regulatory documents, incorrect calculations, or simply errors in the documentation. Although there are advanced methods for identifying and assessing these risks, most of them are not deeply integrated into all laboratory processes, that is, risk management is not only an element of the quality system, but is also carried out as a separate activity. From this point of view, one of the urgent issues is to

systematize the risk management process in laboratories, that is, to integrate it with QMS based on a single, integrated management model. Through this process, the laboratory can assess each of its functional activities based on a risk-based approach and improve its QMS model based on real threats, priorities and control tools [6].

Methodology

This study will scientifically examine how to structure the risk management process, integrate it into the laboratory's quality system, and turn it into an effective management tool.

The first step in risk management is to identify risks, followed by risk analysis and prioritization. The results of this assessment are used to determine measures. It is at this final stage that the question arises of how the assessments of these risks relate to the laboratory's overall quality system. This directly raises the need to systematize risks.

Results and Discussion

The link between risks and QMS is not only achieved by identifying the risk, but also by linking it to the laboratory's:

- quality objectives;
- internal audit plans and analyses;
- corrective and preventive actions;
- stakeholder communication strategy;
- resource allocation;
- service quality monitoring;
- continuous improvement process.

According to the approach developed in this study, risk management is structured around the following key components:

a) risk type. This component indicates which category the risk falls into: human factor, equipment, reagent, environment, document or test sample related. This classification is determined based on the "Laboratory Risk Classification Model" and through this, measures are selected that address each risk;

b) process phase. The phase at which the risk occurs is determined: pre-test, test process and post-test. This description allows for precise control of risks based on their location. This approach works in harmony with the "Process Approach" model;

c) risk analysis and prioritization. The probability (E), impact (T) and control level (N) of the risks are determined and a priority level is determined based on an improved evaluation formula. This value indicates which risk the laboratory should pay attention to first;

d) actions. Once the risk has been identified, preventive or corrective measures are developed depending on its level. These are prepared in relation to the laboratory's current quality objectives, development plan and audit recommendations;

e) monitoring and automation. The most important element of systematization is the presence of constant monitoring of risk factors. For this, it is necessary to use the software we have developed for the risk management system. With the help of this system, the recurrence of risks, the actions taken against them and their effectiveness are regularly analyzed.

By combining these components into a single model, a dynamic and continuously operating risk management system is formed in the laboratory, not a static one. In other words, systematization of risks creates a mechanism for not only assessing them, but also for continuously monitoring, analyzing them, and making decisions based on the results.

Then, the approach:

- increases the operational efficiency of the laboratory;
- allows you to work with the root causes of non-quality situations;
- fully meets the requirements of "risk-based thinking" set out in the ISO/IEC 17025:2017 and ISO 9001:2015 standards [3, 4];
- and most importantly, it stimulates continuous improvement of the quality system.

Risk systematization is considered effective when it is directly applied in practice, not remaining at the level of a theoretical model or assessment formula. To do this, a sequential and interrelated stage system appropriate to the laboratory's activities should be developed. Based on the systematization approach proposed in this article, the risk management process is carried out in the following five main stages:

1. Risk identification. The risk identification phase involves the systematic identification of risk sources within all laboratory processes (pre-test, test process and post-test). At this phase, we propose:

a) risks are listed through group thinking with the participation of laboratory personnel through the "Brainstorming" approach;

b) risks are categorized using a modified "risk classification model": personnel, equipment, reagents, sample, environment, documents and management system.

Through this combination of methods, the identification process is free from subjectivity and becomes systematic and documented.

2. Risk analysis and assessment. For each identified risk, a priority level is determined based on the improved model we have developed. At this stage, the following three criteria are taken into account:

- E (Likelihood) – how often the risk occurs;
- T (Impact) – to what extent the risk harms the laboratory's operations;
- N (Control) – the level of control mechanisms in place to reduce the risk.

Based on these criteria, a numerical priority index is determined for each risk using formula (1). This number serves as the basis for risk ranking. As a result, the laboratory focuses on the most relevant risks.

$$R = \frac{E \cdot T}{N}. \qquad (1)$$

3. Prioritization and assessment of risks. The assessed risks are visually classified based on a matrix or diagram depending on the level of priority [5].

The scope of actions and the form of monitoring for each priority level differ. This allows for the correct allocation of resources and the formation of a proportional approach to risk.

4. Development and digitization of actions. Based on the results of the assessment, for each risk:

a) preventive or corrective actions are determined;

b) these actions are assigned a responsible person, a deadline for implementation and a monitoring method;

c) the actions are integrated into the laboratory software system we have developed, that is, digitized.

This stage forms a system of activity-based actions within the organization to combat risks. These actions are placed in the system using an automation approach.

5. Monitoring and systematic analysis of risks. The last, but most important, stage of the risk systematization process is continuous monitoring and improvement. At this stage:

- risk situations and the implementation of countermeasures against them are systematically monitored;
- reports, indicators, audit results and user feedback are the basis for monitoring;
- the level of recurrence of risk situations is assessed using statistical analysis;
- as a result, the assessment and prioritization process is restarted based on new data - a cyclical model is formed.

Improving the quality management system in a laboratory through risk management is not limited to risk assessment alone. The main goal is to integrate the results of this assessment with the laboratory's controls and to conduct all laboratory activities based on risk-based thinking.

This approach is directly related to a number of important requirements of the ISO 9001:2015 and ISO/IEC 17025:2017 standards.

Table 1. Integration according to ISO 9001:2015 standard

ISO 9001:2015 requirement	Appropriate activities in risk management
6.1. Actions to address risks and opportunities	Based on the risks assessed through the model we developed, priorities are determined and incorporated into the quality system.
8.5.1. Control of production and service provision	Each laboratory process is controlled based on the level of risk.
9.1. Monitoring, measurement, analysis and evaluation	Monitoring of assessed risks is carried out through a digital system.
10.2. Nonconformity and corrective action	Corrective/preventive measures are planned for the assessed risks.
10.3. Continual improvement	The system is re-evaluated based on dynamic analysis of risk situations through software

Table 2. Integration according to ISO/IEC 17025:2017 standard

ISO/IEC 17025:2017 requirement	Contact with risks
8.5.1. Risk and opportunities	The results of the risk analysis are monitored and continuous changes are made to the laboratory's operations.
8.7.1–8.7.3. Nonconformity Management	High risks identified as a result of the assessment are recognized and formalized as non-conformities.
7.10. Noncorforming work	Dangerous situations that occur during the process are automatically detected and recorded in the system.
6.6. Externally provided products and services	Equipment risks are assessed based on a separate control model.
8.9. Management reviews	The results of risk monitoring serve as the basis for management's strategic decisions.

One of the most important aspects of this integration process is that the model we developed and the system it underpins directly link risks in the laboratory to quality indicators. Through this model, each risk is assigned to the appropriate management strategy based on its priority level.

Table 3. Integration directions depending on the priority of the risk

Priority level	Control mechanism in the laboratory
Critical	The risk is recognized as a strategic risk of the laboratory. It is under the direct control of management, is included as a separate indicator in the annual quality goals. A special risk notification and an emergency action plan are developed in the software system.
High	A risk is considered a risk that directly affects the laboratory's operational activities. These risks are included in the internal audit plans for specific checks. At the same time, continuous monitoring is established and documented as control indicators.
Middle	These risks require additional monitoring and preventive measures. They pose a certain risk to the current activities of the laboratory, but do not require immediate intervention. The risk profile is recorded as a low-priority alert in the software system.
Low	These risks have a minimal impact or are under sustainable control through the existing control system. Such risks are monitored through planned controls and regular monitoring. No active action is required, but are included in the cycle of repeated analysis.

In this way, the laboratory transforms its QMS not only at the document level, but into a real active management system based on risk assessment, action, and monitoring.

Conclusion

Thus, the relationship between risk management and the quality system is not a secondary, but a functionally related element. Risks are seen not as a sign of poor laboratory performance, but as one of the indicators of quality management.

In other words, the model for identifying, analyzing and prioritizing risks that we have created can become not only a safety factor for the laboratory, but also one of the main mechanisms of the quality system. By systematizing this, it becomes possible to strengthen the QMS with real processes.

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