E-ISSN: 2997-9382

SemantJournals

American Journal of Technology Advancement
https://semantjournals.org/index.php/AJTA

| Research Article

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Development of a Process Approach Model in Risk Analysis of Analytical Testing Laboratories

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Annotation

The international standard ISO 31000:2018, which includes a procedure for risk management, identifies risk analysis as one of the important steps in the risk assessment process. Risk analysis involves a complete understanding of the risk, drawing conclusions on the information, strategies and methods for making decisions about the need for risk assessment and additional interventions to eliminate these risks.

Risk analysis involves considering the causes and sources of risks, their positive and negative impacts, and the likelihood of these impacts occurring. It is necessary to identify the factors affecting the impacts and likelihood. Risk is analyzed by determining the impacts and likelihood, as well as other characteristics of the risk.

This article describes a model developed using the process approach principle of the quality management system for analyzing risks in analytical testing laboratories. The Ishikawa diagram and the "Bow-tie" methods were used to develop this model.

Keywords: analytical testing laboratory, risk management, risk analysis, process approach, quality management system, Ishikawa diagram, “Bow-tie” method.

Introduction

It would be wrong to say that risk management issues were not previously included in the scope of the testing laboratory management system at all. In particular, in the current ISO/IEC 17025:2017 in paras. 4.12.2 and 5.4.5.3 the risk is mentioned in the context of the need to take it into account when making decisions. But the new edition of the standard moves from accounting requirements to risk management, that is, it establishes the need to develop a full-fledged procedure, the object of which is risks [1].

What should the testing laboratory understand by risk? ISO 31000:2018 defines “risk” as “the effect of uncertainty on objectives”. Risk is often (almost always) associated with an event (the

result of an action or process), including the decision not to take action (saving the current state) [2]. Risk always entails consequences, which may be negative, positive or negligible.

Like most systems in the management system, the quality system and the risk management system are based on principles that serve as a single and integrated framework. The principles underlying the ISO 9001 and ISO 31000 standards are similar in many ways and are compatible with each other. Let us consider and compare the principles of both standards [2, 3].

Table 1. **Principles of quality management system and risk management system** [8]

Principles of quality management	**Risk management principles and its possibilities**
1. Customer focus	Risk management protects the wealth created for the consumer.
2. Leadership	In risk management, management does not avoid risks, but rather skillfully manages them, achieving maximum efficiency of the organization's activities.
3. Process approach	Managing the activities of the laboratory as a process system, it is necessary to take into account all types of risks and create all necessary prerequisites for their identification.
4. Engagement of people	Achieving the set goals is achieved through the direct participation of all employees in risk management.
5. Evidence-based decision making	Risk management allows you to identify the most reliable trends, which helps you make more effective and objective decisions.
6. Relationship management	Risk management makes the collaboration process more transparent and mutually beneficial.
7. Improvement	Risk management, like quality management systems, helps to continuously improve all activities.

The process approach, as shown in the table above, is a management method that aims to improve the efficiency of all laboratory activities by considering them as interconnected processes. This approach is defined as one of the basic principles in the ISO 9001 and ISO/IEC 17025 standards.

Methodology

This study was conducted based on the process approach principle of ISO 9001:2015 and the “bow-tie” and Ishikawa diagram methods of risk analysis of IEC 31010:2019 [4].

An incident can have multiple impacts and affect different objectives. In general, it can be said that the main task at the risk analysis stage is to select strategies and methods for all stages after the identification of risks [5].

Classical approaches to risk analysis in analytical testing laboratories are often based on separate stages, specific conditions or objects. However, laboratory processes are interconnected, complex and dynamic, and each stage of them has a certain level of risk. Traditional analysis methods (Ishikawa, “Bow-tie”, etc.) cannot fully cover the complexity and specific aspects of laboratory activities. Therefore, an integrated model that covers the entire process flow and assesses the likelihood and consequences of risks at each stage is necessary.

An improved model of this method is considered as a scientific and practical result of the research.

Results and discussion

Processes in analytical testing laboratories are divided into 3 main types (Figure 1).

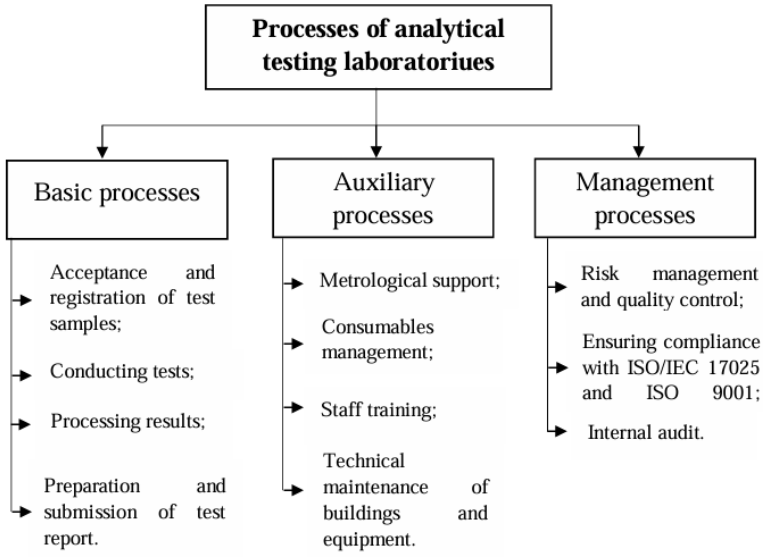

Figure 1. Classification of processes in analytical testing laboratories.

While the primary processes serve to fulfill the primary tasks of the laboratory, the supporting processes ensure the smooth operation of the laboratory. The overall strategy and quality system management of the laboratory belong to the management processes [6, 7].

After the risk identification phase has been successfully completed, one of the next important steps is an in-depth risk analysis.

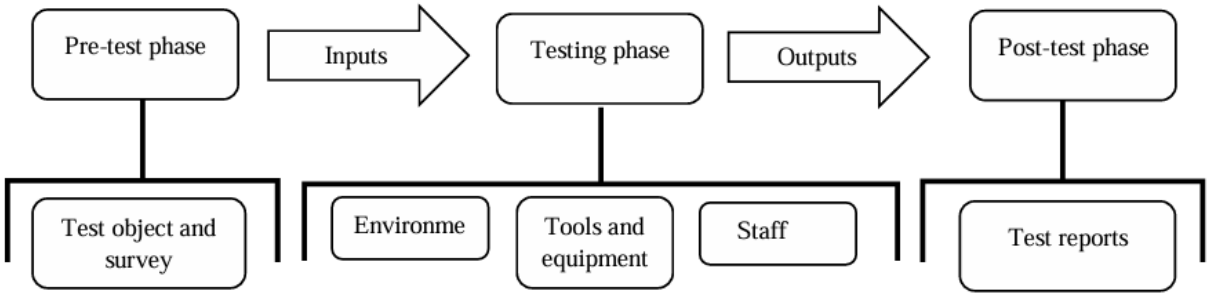

Figure 2. Process approach to analytical testing laboratory risk analysis.

This approach (Figure 2) has input, process, and output stages, in which:

- the model is divided into sequential processes such as the pre-test phase (input), the test phase (main process), and the post-test phase (output);
- at each stage, specific tasks are performed and this result is transferred to the next phase;
- the model is organized based on the process approach of ISO 9001:2015 and is aimed at continuous improvement of laboratory processes;
- each element in the test process (staff or personnel, environment, equipment, etc.) is interrelated and directly affects the quality of the process;
- the model takes into account the interaction of these elements and develops measures to minimize their risks.

The process approach according to ISO 9001:2015 is used to increase the efficiency of the organization and ensure continuous improvement. This approach is based on the basic Plan-Do-

Check-Act (PDCA) principle, and below we have linked this PDCA cycle to the process approach model for laboratory risk management.

The model was developed in accordance with the process approach of ISO 9001:2015 and is aimed at managing and optimizing laboratory risks. We considered its main advantages to be:

- ✓ systematic management of laboratory processes;
- ✓ continuous integration of risk identification, assessment and mitigation;
- ✓ compliance with ISO/IEC 17025 and ISO 9001 standards;
- ✓ the possibility of digitalization and automation.

Table 2. **Adapting the risk management model to the requirements of the process approach according to the ISO 9001:2015 standard**

ISO 9001:2015 approaches	The laboratory's relationship to the risk management process
Process navigation	The laboratory manages risks as a sequence of processes: risk identification → assessment → determination of actions → monitoring.
PDCA principle	Each risk is identified (Plan), assessed and acted upon (Do), results are monitored (Check), and the system is improved (Act).
Risk-based thinking	The laboratory increases reliability and quality by identifying and assessing risks.
Digital and automated control	Risk identification and control are carried out through a digitalized and automated system.
Continuously improve the efficiency of processes	The method we have developed allows for continuous improvement and real-time monitoring of risks.

In this study, a special model based on a process approach for risk analysis in laboratories, using the Ishikawa diagram and the "bow-tie" method, was developed. This model allows each risk to be analyzed in the context of the internal processes associated with it.

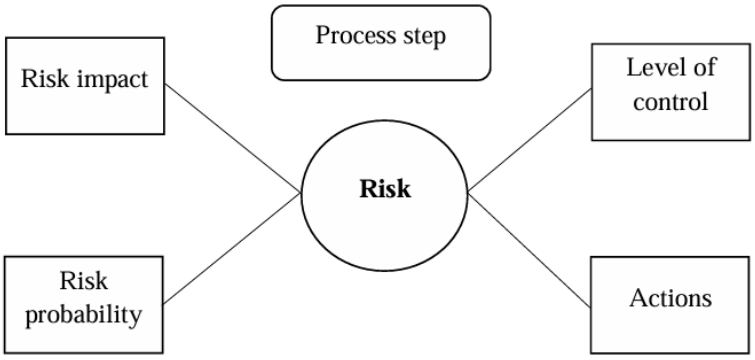

Figure 3. Proposed modular block diagram model for risk analysis.

This model, which reflects a process approach to risk analysis, allows for a comprehensive analysis of risks arising at each phase, while maintaining the continuity of laboratory processes.

At the heart of the model, each risk is considered as a separate object and is analyzed using the following key parameters:

- ➢ process phase - determines at what phase the risk occurs (pre-test, testing phase or post-test);

- risk impact - determines what negative consequences the risk will have on laboratory processes, personnel, equipment or product quality if the risk occurs;
- risk probability - expresses the likelihood of the risk occurring;
- control level - assesses the adequacy of existing control measures or system level against this risk;
- actions - a set of preventive and corrective actions planned or implemented to reduce or eliminate the risk.

Below we present our results of comparing this model with traditional methods.

Table 3. **Comparative analysis of the model with traditional methods**

Indicators	**Ishikawa diagram**	**Bow-tie**	**The proposed model**
Direction of analysis	Based on causal analysis	The relationship between causes and effects	Cause-process-effect chain(
Consideration of processes	Limited	Grouping	Every process step of the laboratory is analyzed
Covering complex processes	Limited	Middle	Highly comprehensive
Visual expression	Fishbone	Bow-tie shape	Modular block diagram
Risk class relationship	Indirectly	Indirectly	Directly (employees, management, etc.)

Each laboratory risk is analyzed through a three-step process:

1. Causes – the factors that lead to the occurrence of the risk;

2. Process – how the risk is formed and propagated;

3. Impacts – the negative consequences that result from the risk.

By identifying these three steps, it is possible to analyze each risk chain and create a basis for further assessment.

Conclusion

This approach covers the main stages regulating the laboratory testing process and integrates risk management into it. The model developed through this approach is aimed not only at identifying risks at each stage of laboratory activities, but also at analyzing, assessing and controlling them, and is developed in accordance with the requirements of ISO/IEC 17025:2017 and ISO 9001:2015 standards.

As the level of scientific innovation of the model, we can cite the following:

1) the model allows for a step-by-step analysis of laboratory processes, which serves to more accurately identify the source and direction of risk;

2) there is a possibility of separate assessment for each risk based on external and internal factors, which helps to more deeply manage laboratory safety;

3) the model is a practical, integrated solution, created based on the analytical power of Ishikawa and “bow-tie” method and the systematic nature of the process approach;

4) through this approach, risk analysis in laboratories is prepared for the stages of digitization and automation, which is integrally linked to the next stages of the quality management system.

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