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IMPROVING THE INTEGRATED RISK IDENTIFICATION SYSTEM IN ANALYTICAL TESTING LABORATORIES BASED ON CLASSIFICATION AND PROCESS-ORIENTED METHODOLOGIES

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A B S T R A C T

The accuracy and reliability of test results in analytical testing laboratories significantly depend on the correct and effective management of operational risks. This paper proposes a methodology to enhance risk identification efficiency by categorizing potential hazards into four primary classes: "Personnel", "Management", "Reagents and Equipment", and "Environment and Samples". Such an approach enables laboratory managers to conduct a systematic search for risks within specific operational domains. Furthermore, the identified risks are integrated into a three-stage functional flow model, wherein pre-testing, testing-period, and post-testing processes are analyzed independently. The proposed model simplifies the risk identification process and serves to improve the laboratory quality management system in accordance with international standards, specifically ISO/IEC 17025. Implementation of this integrated framework helps in minimizing human-related errors and optimizing resource allocation across different laboratory workflows. Application of the framework in an accredited laboratory environment resulted in the identification of previously unrecognized risk factors, demonstrating improved diagnostic coverage and enhanced structural consistency of the risk management process.

1. INTRODUCTION

Sample analysis is a fundamental daily practice for more than 60,000 laboratories worldwide. Vasilnakova (2018) emphasized that the fundamental mission of testing organizations is to furnish clients with rigorous assurances and guarantees concerning the precision of analytical findings. This strategic commitment serves as a primary vehicle for laboratories to substantiate their technical proficiency and operational competence in the delivery of high-fidelity data. Guided by Clause 8.5 of the ISO/IEC 17025:2017 standard, testing and calibration

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laboratories are required to strategically plan interventions for managing risks and opportunities inherent in their operations. This systematic methodology is indispensable for neutralizing adverse impacts, mitigating operational vulnerabilities, and fostering a culture of continuous improvement within the laboratory management framework.

The occurrence of risks in any laboratory is an inherent part of its operations. Drawing upon the "risk-based thinking" philosophy pioneered by the ISO 9001:2015 standard, laboratories are encouraged to integrate customized risk management methodologies as a fundamental pillar in the formulation and execution of management decisions.

2. LITERATURE REVIEW

Silva et al. (2021) demonstrated that by systematically identifying high-risk domains, quantifying their potential impact, and ensuring consistent monitoring, uncertainties can be effectively mitigated or contained within acceptable thresholds. This proactive orientation significantly attenuates risk levels and curtails adverse consequences that could compromise the integrity and reliability of analytical datasets.

As stipulated in the ISO 31000:2018 (2018) standard, the risk assessment architecture within testing laboratories is structured around three foundational stages: risk identification, analysis, and evaluation. This international guideline establishes a robust framework for the seamless integration of risk management across all operational dimensions of an organization. However, the specific characteristics of analytical laboratories necessitate the application of more specialized and systematized classification methods when performing these risk assessment stages.

Current academic literature and practical implementations frequently rely on static, checklist-based risk identification methodologies. As noted by David (2022), Chang et al. (2021), and de Jesus et al. (2023), such traditional approaches are often tenuously linked to laboratory operational workflows and lack the robustness required for systematic risk analysis across diverse testing stages. Despite the increasing emphasis on risk-based thinking within ISO/IEC 17025, existing studies predominantly focus on compliance-oriented checklists or isolated analytical techniques that treat risks as static elements rather than dynamic process-dependent factors.

The limitations of conventional checklists are further exacerbated by what Mazunina et al. (2021) describe as a persistent lag in management modernization within the digital economy. Their research highlights a critical systemic gap: while advanced technologies are widely accessible, quality management practices often remain tethered to traditional, low-tech orientations, resulting in moderate effectiveness and unsustainable competitive advantages. To address this "modernization lag" the present study introduces a scalable, process-oriented classification framework designed to align laboratory risk identification with the dynamic requirements of high-tech analytical environments.

While existing research underscores the significance of risk-based thinking within laboratory quality management, a noticeable gap remains regarding structured models that directly synthesize risk identification with functional process stages. To bridge this critical gap, the present study introduces a process-oriented and classification-based framework specifically designed for risk identification and analysis in ISO/IEC 17025-accredited analytical testing environments.

Building upon our previous longitudinal research (Erkaboev et al., 2023; Erkaboyev & Masharipov, 2024), which critically evaluated the integration of ISO 9001 risk management models and the operationalization of monitoring systems in accredited environments, the present study introduces a significantly more refined and granular approach to risk identification. While our earlier works focused on the general framework and compliance with international standards, the current paper aims to enhance the integrated risk identification system by categorizing potential risks into four primary classes: "Personnel", "Management", "Reagents and equipment", and "Environment and samples". By integrating these specific classes into a three-process functional flow model – comprising pre-testing, testing-period, and post-testing processes – this research provides a comprehensive methodology for optimizing laboratory quality management in accordance with ISO/IEC 17025.

The scientific novelty of this study lies in the integration of a functional risk classification with a process-approach laboratory workflow, enabling systematic identification and qualitative analysis of risks beyond traditional checklist-based approaches.

Unlike existing checklist-based or tool-specific approaches, this study contributes a structured integration of functional risk classification with process-oriented laboratory workflows, enabling systematic identification and qualitative analysis of risks across the full analytical lifecycle.

3. METHODOLOGY

As articulated by Tziakou et al. (2023), the core objective of risk identification and analysis is to systematically discover, recognize, and characterize uncertainties that may either catalyze or impede a laboratory's progress toward its strategic objectives. During the identification phase, the relevance, suitability, and temporal accuracy of the utilized data emerge as critical determinants of success. By documenting potential risks, practitioners can capture those multifaceted factors that influence the entire operational spectrum of the facility. Consequently, this stage serves as an indispensable prerequisite for effective risk management throughout the analytical lifecycle, providing the essential empirical foundation and primary input for all subsequent risk analysis activities.

Furthermore, the IEC 31010:2019 (2019) standard offers a comprehensive suite of methodologies designed to assist laboratories throughout both the risk identification and analysis phases. These tools encompass diverse domains, including sophisticated data collection techniques, rigorous data analysis protocols, and essential interpersonal or team-based competencies. While these tools offer a broad range of options for general risk management, their application in analytical laboratories is frequently hindered by a lack of specialized structure. Traditional methods often rely on generic checklists or focus primarily on technical non-conformities, which can be fragmented and unsystematic. Many laboratories struggle to integrate these generic tools into a cohesive workflow that simultaneously identifies and analyzes specific risks leading to inconsistent results. Consequently, there is a clear need for a more integrated classification that aligns these international standards with the functional reality of testing processes, ensuring that risks are not only found but also systematically characterized.

To systematically evaluate existing approaches, a comparative analysis of common risk identification and analysis techniques was conducted by the author, as presented in Table 1.

Table 1. Comparative analysis of risk management methods

Method	Time expenses	Data input require-ments	Expert expe-rience	Implemen-tation complexity
Risk identification				
Brainstor-ming	Low	Low	Moderate	Low
Expert assessment	Low	Low	Moderate	Medium
Delphi method	High	Low	Moderate	Medium
Risk analysis				
Bow-tie	Low	Low	Moderate	Low
FMEA FMECA	Medium	High	Moderate	High
FRACAS	Medium	High	Moderate	High

The analysis reveals that while simplified methods like brainstorming require minimal resources, more robust analytical tools such as FMEA/FMECA or FRACAS involve significant data input and high implementation complexity. This evaluation confirms the necessity for the integrated model proposed in this study, which aims to bridge the gap between resource efficiency and analytical depth.

Based on the comparative analysis presented in Table 1, it is evident that choosing an appropriate risk management methodology involves a trade-off between resource consumption and analytical precision. Techniques such as Brainstorming and the Delphi method are accessible in terms of time and data requirements, yet they often lack the depth needed for complex analytical environments. Conversely, robust analysis tools like FMEA/FMECA and FRACAS provide high-level precision but impose a significant burden on the laboratory due to high data input requirements and implementation complexity. For many laboratories, particularly those operating under tight operational schedules, these traditional methods can be overly labor-intensive, leading to inconsistent application. Therefore, there is a critical need for a model that provides a structured, multi-dimensional classification while maintaining a manageable level of complexity for laboratory personnel.

In light of the limitations identified in conventional methodologies, this research introduces an integrated, process-oriented risk identification framework structured around functional components. Unlike generic checklists, this model systematically partitions the laboratory's operational ecosystem into four core risk sources: "Personnel", "Management", "Reagents and Equipment", and "Environment and Samples". This classification acts as a diagnostic lens, allowing specialists to pinpoint latent risks within specific functional layers that are often overlooked by standard procedures. By isolating these components, the laboratory can transition from a reactive "find-and-fix" approach to a proactive, categorized analysis where the root causes of potential failures are clearly mapped to their respective operational domains.

To provide a more granular understanding of laboratory uncertainties, this research introduces a hierarchical classification model as illustrated in Figure 1.

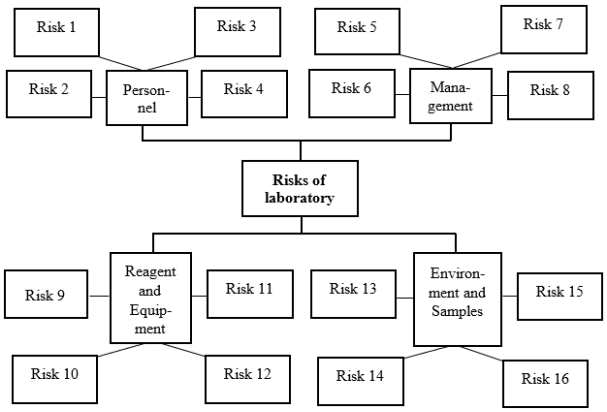

Figure 1. Proposed hierarchical classification model for risk identification in analytical testing laboratories

The model systematically categorizes potential risks into four foundational dimensions: "Personnel", "Management", "Reagents and Equipment", and "Environment and Samples". Each dimension acts as a primary cluster that encompasses specific risk factors – denoted as Risk 1 through Risk 16 – which are directly linked to the analytical testing process. The numerical designations (Risk 1 to Risk 16) in the proposed model serve as a dynamic template; they represent placeholders that can be substituted or expanded with specific, real-world risks identified by any laboratory during its operational diagnostic phase. This modular structure ensures the framework's scalability, allowing for the inclusion of an unlimited number of identified

uncertainties within the four functional domains. This structured mapping allows for the precise isolation of risk origins, ensuring that the identification and analysis stages address both direct technical failures and indirect organizational vulnerabilities.

The proposed hierarchical model categorizes potential risks into four functional domains directly surrounding the analytical process. Each domain represents a critical cluster of uncertainties that can affect the quality and safety of laboratory operations:

1) "Personnel": focuses on human-centric risks originating from analysts and management staff. Key factors include deviations from standard operating procedures, insufficient safety awareness, and technical competency gaps;

2) "Management": addresses systemic errors in laboratory governance. This includes inadequate safety protocols, a lack of comprehensive professional development strategies, and issues regarding laboratory competence or the provision of current regulatory documentation;

3) "Reagents and Equipment": risks in this domain emerge from two primary directions. First, the chemical stability and storage integrity of reagents, including expiration and leakage issues. Second, the metrological reliability and physical aging of instruments, alongside deficiencies in safety management systems;

4) "Environment and Samples": environmental factors are analyzed through working conditions (e.g., electrical safety), storage parameters (temperature, humidity, pressure), and external natural influences. Simultaneously, this domain covers the lifecycle of the sample – from normative selection and volume sizing to transportation and preservation.

The systematic implementation of this functional model serves as a comprehensive roadmap for identifying all primary risk factors within the laboratory environment. By establishing these categorical boundaries, the process provides a clear directional framework for the subsequent stages of risk analysis and evaluation. This structured approach ensures that each identified uncertainty is not merely listed but is strategically funneled into a quantitative or qualitative assessment phase, where its impact on analytical reliability can be rigorously measured.

Habibie and Basuki (2019) characterized the operations of analytical testing laboratories as a matrix of intricate and interconnected workflows, emphasizing that each procedural stage is inherently susceptible to a diverse array of risk factors. For risk management to be effective, it is imperative to identify, analyze, and monitor these uncertainties within the specific context of operational processes. Consequently, modeling laboratory activities through a process-oriented approach becomes essential. This methodology allows for the decomposition of complex testing cycles into manageable stages, ensuring that risk analysis is not a static observation but a dynamic evaluation of the entire analytical lifecycle. By mapping risks to these functional stages, the laboratory can achieve higher precision in predicting potential failures and implementing targeted mitigation strategies.

Following the successful identification of risks, the subsequent critical phase involves an in-depth analysis of these uncertainties. Rooted in the process-approach principle of quality management systems, a specialized mechanism has been developed to decompose analytical testing into three distinct operational phases: pre-testing, the testing period, and post-testing. This granular approach facilitates a dynamic evaluation where risks identified in the hierarchical model are analyzed within their specific temporal context. As illustrated in Figure 2, this framework ensures that uncertainties ranging from sample procurement to final report generation are systematically characterized, providing a streamlined pathway for risk prioritization.

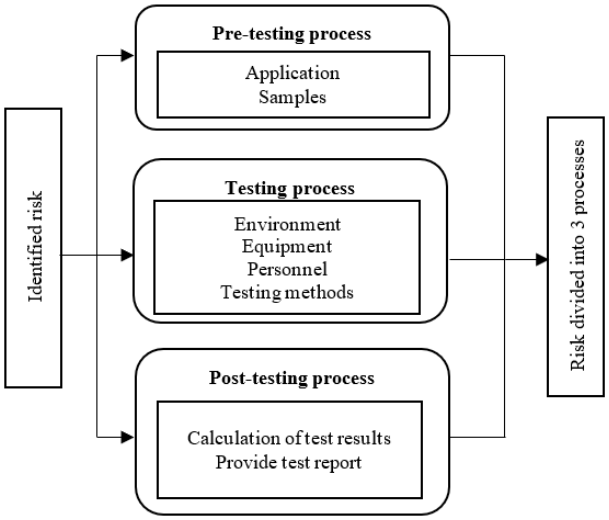

Figure 2. Functional flow model for three-process risk analysis in analytical testing laboraotry

The operational logic of the three-process risk analysis model, as depicted in Figure 2, ensures that identified risks are evaluated throughout the entire analytical lifecycle. This framework partitions laboratory activities into three distinct stages to facilitate targeted risk mitigation:

- pre-testing process: focuses on the initial phase where risks related to the testing application and sample integrity are scrutinized;
- testing process: represents the core analytical stage where environmental conditions, equipment reliability, personnel actions, and adherence to testing methods are analyzed simultaneously;
- post-testing process: addresses the final phase, ensuring the accuracy of test result calculations and the formal provision of the test report.

This functional flow allows for the systematic division of risks into three manageable processes, providing a structured data output for the subsequent evaluation and prioritization phase. The proposed framework contributes to quality and risk management practice by structuring risk identification around laboratory functional processes rather than isolated events. Unlike conventional approaches that rely primarily on predefined checklists, this framework facilitates the

identification of both explicit and latent risks through systematic process mapping and functional analysis. As a result, the framework enhances the analytical depth of risk identification while maintaining alignment with the principles of ISO/IEC 17025 and established quality management systems.

4. MATHEMATICAL MODEL

In this paper we proposed integrated risk identification model represents a process-oriented framework designed to improve operational risk detection within analytical testing laboratories operating under quality management principles of ISO/IEC 17025:2017. The model structures risk identification into four primary functional domains: Personnel, Management, Reagents and Equipment, and Environment and Samples, as it was defined in previous sections. This model will enable systematic classification of potential uncertainties within the laboratory ecosystem. Each functional domain contains specific risk factors that can be dynamically expanded depending on operational requirements, allowing the framework to maintain scalability across different laboratory settings. The model integrates a three-stage workflow decomposition consisting of pre-testing, testing-period, and post-testing processes, which supports temporal mapping of risk occurrences across the analytical lifecycle.

By combining hierarchical risk classification with process-based operational segmentation, the model shifts laboratory quality management from fragmented checklist-style assessment toward structured analytical monitoring. The framework is intended to enhance diagnostic visibility of latent operational risks, support proactive decision-making, and improve internal audit readiness. The model is particularly suited for laboratories seeking to implement risk-based thinking strategies while maintaining methodological simplicity and practical applicability in real operational environments.

Let the overall risk evaluation system be defined as an aggregated functional model.

$$R_{total} = \sum_{i=1}^{4} w_i C_i + \sum_{j=1}^{3} v_j P_j$$

where:

- Ci – Classification risk score for four functional domains: Personnel; Management; Reagents and Equipment; Environment and Samples.
- Pj – Process risk score for three operational phases: Pre-testing; Testing-period; Post-testing.
- wi – Weighting coefficients of the classification domains.
- vj – Weighting coefficients of the process phases.

4.1 Classification Risk Score

For each functional domain, the following are defined:

$$C_i = \frac{\sum_{k=1}^{n_i} r_{ik} \cdot s_{ik}}{n_i}$$

- r_{ik} – identified individual risk factor
- s_{ik} – severity or operational impact score
- n_i – number of risks within the class

4.2 Process Risk Score

$$P_j = \frac{1}{m_j} \sum_{t=1}^{m_j} d_{jt}$$

where:

- d_{jt} – detektovani rizik u procesu j
- m_j – broj workflow tačaka u fazi j

4.3 Normalization of the Model

For system stability, min–max normalization is used:

$$R^* = \frac{R_{total} - R_{min}}{R_{max} - R_{min}}$$

This enables comparison of laboratories of different sizes.

4.4. Empirical Comparative Validation

4.4.1 Experimental Design

We suggest paired laboratory assessment protocol:

Group	Method
Control model	Checklist-based risk identification
Experimental model	Proposed integrated framework

4.4.2 Performance indicators

(1) Risk detection yield

$$\Delta N = N_{proposed} - N_{baseline}$$

$$Improvement\ Rate = \frac{\Delta N}{N_{baseline}} \times 100\%$$

(2) Inter-rater reliability

Cohen's kappa coefficient:

$$\kappa = \frac{P_o - P_e}{1 - P_e}$$

where:

- Po – observed agreement
- Pe – expected random agreement

(3) Workflow coverage index

$$WCI = \frac{T_{covered}}{T_{total}}$$

- Tcovered– number of process points covered by the model
- Ttotal – total number of laboratory workflow points

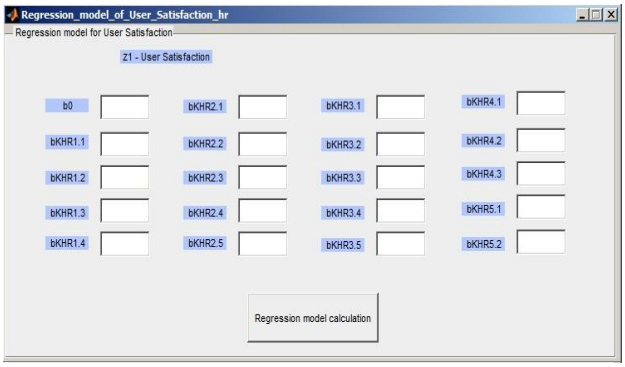

Figure 3. Using MATLAB, we simulated the KPI values for all four dimensions.

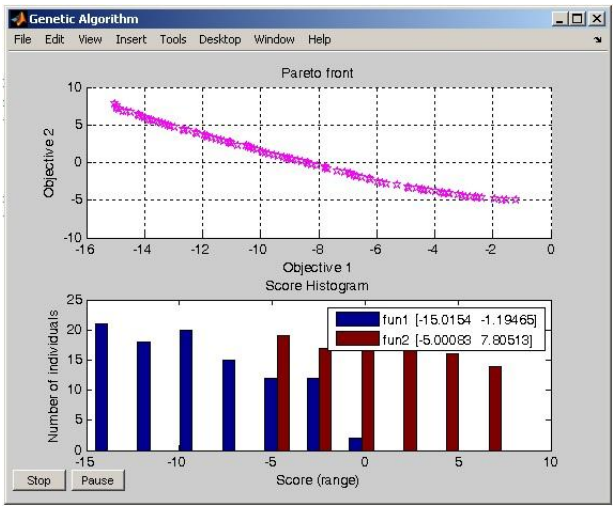

Figure 4. Pareto-optimal solutions for ranking the KPIs of a subprocess

To quantitatively assess the effectiveness of the proposed risk identification framework, we employed MATLAB simulations to model KPI values across all four functional domains: Personnel, Management, Reagents & Equipment, and Environment & Samples. This computational approach allowed for a systematic evaluation of each domain's contribution to overall laboratory risk exposure, ensuring that both direct and latent uncertainties were captured (Figure 3). Furthermore, by applying Pareto-optimal analysis to rank KPIs within individual subprocesses, we were able to identify priority areas for targeted intervention, highlighting the points in the laboratory workflow where risk mitigation would have the greatest impact (Figure 4). This integration of simulation-based KPI modeling with process-oriented risk classification not only reinforces the rigor of our methodology but also provides laboratory managers with a practical, data-driven tool for proactive decision-making and quality optimization.

5. RESULTS AND DISCUSSIONS

Currently, more than 230 testing laboratories operate within the Republic of Uzbekistan. The empirical research for this study was conducted at the testing laboratory of the "Uz Test" State Institution (SI) Fergana Branch. This facility is accredited in accordance with the O'z DSt ISO/IEC 17025:2019 standard and specializes in the analytical testing of food and agricultural products, as well as polymer-chemical, perfumery, and cosmetic goods.

Application of the proposed framework enables systematic traceability of risks across laboratory processes and supports more consistent identification of potential nonconformities in compliance with ISO/IEC 17025 requirements.

Prior to the implementation of the proposed model, the laboratory had identified only 22 risk factors using conventional qualitative methods. By applying the systematic functional component-based methodology, a total of 32 distinct risk factors were successfully identified. The distribution of these risks across the four primary classes was perfectly uniform, with 8 risks identified in each category, as illustrated in Figure 5.

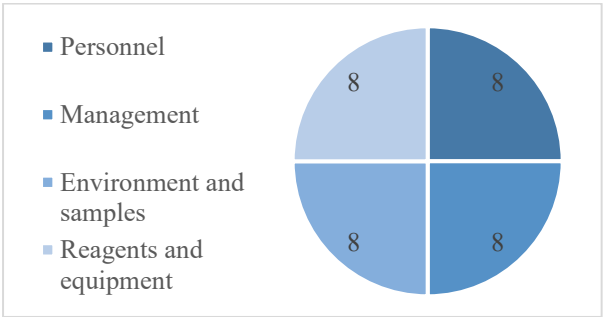

Figure 5. Distribution and classification of identified operational risks across four functional components: A case study of an ISO/IEC 17025 accredited environment.

By structuring these uncertainties into four functional components and three operational stages, the study successfully uncovered 10 previously undetected "latent" risks. The identification of 10 additional risks is not a reflection of increased operational risks, but rather an indicator of the enhanced diagnostic sensitivity provided by the proposed integrated framework. By transitioning from a fragmented checklist approach to a structured process-approach, the model successfully eliminated "blind spots" in the risk landscape. This expansion of risk visibility proves that the proposed methodology provides a more robust foundation for the laboratory's quality management system, uncovering latent vulnerabilities that standard procedures often overlook. This outcome demonstrates that a process-oriented approach is critical for transitioning laboratory management from reactive correction to proactive risk-based thinking.

The process-oriented modeling developed in this study provided a clearer visualization of risk sources within the laboratory workflow. This approach enabled the identification of risk density at specific stages, allowing for the determination of priority areas for subsequent evaluation. The 32 identified risks were distributed across the laboratory processes as follows:

1) pre-testing process: 10 risks;

2) testing-period process: 14 risks;
3) post-testing process: 8 risks.

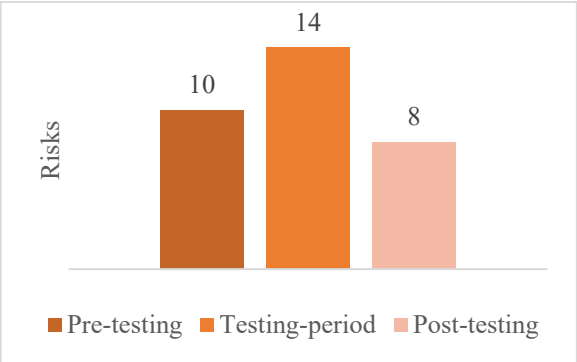

Figure 6. Quantitative analysis of risk density across the three-stage analytical testing lifecycle in the laboratory.

Analysis of these results, as illustrated in Figure 6, reveals that the most vulnerable point in the laboratory's quality system is the active testing process. Systematizing the risks by process stages highlights where uncertainties are concentrated and indicates which directions should take priority in the risk management strategy.

The analysis demonstrates that the proposed framework improves the structural coherence of risk identification by systematically integrating functional components with process stages. This integration enables clearer visualization of risk concentration within laboratory workflows and supports more consistent prioritization of risks across operational phases.

This structured integration of functional and process-based elements allows risk identification activities to move beyond fragmented assessments toward a more holistic representation of laboratory operations. By revealing the distribution of risks across operational processes, the framework supports a clearer understanding of how procedural interdependencies influence risk concentration within accredited analytical testing laboratories.

5. CONCLUSIONS

The research successfully implemented an integrated risk identification and analysis framework at the "Uz Test" SI Fergana branch. By transitioning from a generic identification process to a structured model based on functional components and operational stages, the laboratory's risk visibility was expanded from 22 to 32 identified risks.

The key conclusions of this study are:

1) systemic identification: dividing risks into four classes ensures a balanced and comprehensive oversight of the entire laboratory ecosystem;

2) process priority: mapping risks to the analytical lifecycle revealed that the active testing stage is the most critical phase, accounting for 43.75% of identified uncertainties;

3) strategic shift: The proposed methodology facilitates a shift from reactive correction to a proactive, risk-based thinking approach, as required by O'z DSt ISO/IEC 17025:2019.

Compared to conventional checklist-based approaches, the proposed model provides improved structural clarity and process integration, which can facilitate preventive actions and enhance internal audit preparedness in analytical testing laboratories.

The results of this study show that combining risk classification with process-oriented workflow decomposition can improve understanding of operational uncertainties in analytical testing laboratories. The proposed framework represents a step toward more structured, model-based laboratory risk management.

The increase in identified risk signals observed in simulations does not necessarily mean that laboratory operations are becoming more dangerous; it mainly reflects improved detection capability achieved through hierarchical classification and process segmentation. In checklist-based approaches, some weak or hidden operational risks may remain unnoticed because evaluation is fragmented and depends heavily on expert experience.

Risk distribution across operational stages shows that the testing phase contains the largest proportion of uncertainties due to direct interaction between personnel, equipment, and environmental conditions. Pre-testing activities also show notable risk presence, especially in sample handling and preparation, while post-testing operations carry lower but still relevant risk density related to data processing and reporting.

The framework supports risk-based thinking principles of ISO/IEC 17025:2017 by helping laboratory managers visualize operational vulnerabilities. However, the model was tested mainly through conceptual simulation and single-case implementation, limiting generalizability. Future work should include multi-laboratory validation and development of quantitative scoring algorithms for more precise risk prioritization.

Future work will be dedicated to the development of a mathematical formula for the quantitative evaluation of these identified risks, allowing for precise prioritization and resource allocation in laboratory quality management.

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