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Approaching Risk Management in Medical Laboratories

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Abstract

Risk is one of the greatest challenges in a medical laboratory. Risk-based thinking is a concept that always preoccupies medical laboratory technicians. The objectives of this work were to bring forward the specialty standards recommendations for the implementation of risk management principles in medical laboratory, the accreditation requirement of ISO 15189:2012; to demonstrate that the understanding of the fundamental notions of the concept of risk, the effectively apply of the means of identifying, assessing and controlling risks, and the risk monitoring and handling through strategies of acceptance, elimination, transfer and mitigation of risks can ensure the continuous improvement processes. A model to approach to risk management in a medical laboratory establishes the inputs, the outputs, the techniques, and the activities carried out in each of the following sub-processes of the risk management process: risk management process planning, risk identification, risk analysis and evaluation, development of the risk response plan and risk monitoring, control and revision. The concepts of risk and risk management are applied accordingly to standards ISO 31000:2018 and ISO 22367:2020 of International Organization for Standardization (ISO). Risk management ensures that the fundamental requirements for healthy, proactive internal control of the medical laboratory are met.

Keywords*: quality control and evidence based laboratory medicine*

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1. Introduction

Every organization, regardless of its size, faces internal and external factors that lead to uncertainty concerning the achievement of its proposed objectives (1). According to the ISO Guide 73:2009, section 1.1, risk is "the effect of uncertainty on the achievement of objectives [economic, social, health or safety]" (2). Uncertainty is a context associated with the lack of information regarding an event—the consequences that cannot always be anticipated or that would not have been considered plausible. Currently, there are approximately 40 definitions of risk in 140 ISO standards. ISO 22367:2020 (3) and the Clinical and Laboratory Standards Institute (CLSI) EP18-A2 standard (4) adopted their definition of risk from ISO 51:2014 (5), which consider it as the combination of the probability of occurrence of harm and the severity of its consequences.

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Risk management analysis associates the existing situation with the future desired situation; it has the following purposes:

- early warning for potential nonconforming events (risks) using risk and/ or quality indicators (6) that detect changes in the analyzed process;
- mitigation of the effect/ impact of risks by taking preventive actions (7);
- development of risk response strategies (1).

ISO 15189:2012 brought to the attention of medical laboratories a clause regarding risk management (4.14.6), which states that a laboratory must evaluate the impact of possible working process errors on the patients' health, and thus take actions to mitigate or eliminate risks (8). Thus, medical laboratories had to document and to incorporate risk management into their own quality management system. Without any clear recommended methods from the standard regarding the implementation of risk management, some laboratories choose to develop a risk management methodology following other standard recommendations.

ISO 31000:2018 is an internationally accepted standard based on the idea that risks arising from a lack of organizational order can be controlled through good management and governance. This standard has no detailed instructions on how to identify, analyze, and evaluate risks (1).

The risk management analysis is addressed to each process or department in a medical laboratory and is performed with the participation of all laboratory personnel and relevant stakeholders, with the management of the laboratory presiding over the procedures.

To facilitate risk management based on the medical laboratory requirements of ISO 15189:2012, section 4.14.6 becomes useful the quality management principles described in ISO 9001:2015, namely the process approach. Furthermore, ISO 22367:2020 Annex A introduces the concept of risk-based thinking (this concept that is also present in ISO 9001:2015, which allows the establishment, implementation, maintenance, and continuous improvement of quality management system) in the context of medical laboratory (3, 8, 9).

ISO 9000:2015, section 3.4.1, respectively ISO 15189:2012, section 3.17, define a process as "a set of related or interacting activities that transform inputs into outputs, undertaken to achieve an objective according to specific requirements" (8, 10). A schematic representation of a process shows the interaction between sequences of different stages of its sub-processes facilitating the development of a risk management process approach in a medical laboratory. In accordance with these standards, a medical laboratory, in order to document risk, establishes the inputs, the outputs, the techniques, and the activities carried out in each of the following 5 sub-processes of the risk management process:

- risk management process planning;
- risk identification;
- risk analysis and evaluation;
- development of the risk response plan;
- risk monitoring, control, and revision.

The laboratory can design a template for each sub-process of the risk management process that comprises key elements which must be taken into consideration when risk analysis is performed for any of the processes. Examples of templates for each of the risk management sub-process are illustrated bellow in the article for the pre-analytical process in a medical laboratory.

In the first stage, it is recommended to compare the elements included in each of the 5 sub-processes of the risk management process documented in a medical laboratory (Supplemental Table 1, column A), with the principles, framework, and requirements needed for the risk management process according to ISO 31000:2018 (Supplemental Table 1, column B), thus making sure that the ISO 31000:2018 requirements were

met (1). In the next stage, the laboratory technicians identify the most important processes in the medical laboratory, and their interactions and correlations, which offer a good operation (Supplemental Table 1, Column C). This approach makes available necessary information for the risk management analysis through procedures and connected informational circuits.

Most laboratories have a quality management system (QMS) implemented according to ISO 15189:2012, section 4.2, and its efficiency will be strengthened by adopting the risk-based thinking concept. Supplemental Table 1, column D, mentions the ISO 15189:2012 requirements included in the risk management analysis documented by a medical laboratory (8). ISO 22367:2020 Annex A offers guidance to laboratories that have implemented ISO 15189:2012 on how to incorporate risk management in appropriate parts of their QMS (Supplemental Table 1, Column E) (3).

ISO 22367:2020 suggests that the risk management process should include the following elements: risk management plan; risk analysis; risk evaluation; risk control; risk management review; risk monitoring (3).

2. The Risk Management Process

Risk management process planning

Risk management process planning represents the sub-process in which it is decided how to approach the risk management activities for the selected process in a medical laboratory. Planning has the aim of transforming the principles and guidelines of risk management into decisions and actions (e.g., laboratory policy regarding risk management) that can contribute to the development of a methodology adapted to the medical laboratory regarding risk management (Risk Management Plan), whose implementation derives from the necessity to apply quality and risk standards required by accreditation organizations in the medical laboratory. According to ISO Guide 73:2009, section 2.1.3, the risk management plan (RMP) is a "program included in the framework of risk management that specifies the approach, management components (procedures, practices, assignment of responsibility, succession and activities schedule) and the resources used in risk management" (2).

Table 1 is an example of a template for the risk management planning sub-process for pre-analytical process of the Biochemistry Department in a medical laboratory, in which it mentions the inputs, tools and techniques used, and outputs of this sub-process.

When elaborating the methodology, a set of fundamental elements and organizational requirements, included in the framework of risk management are taken into account (2).

Leadership and commitment: the policy of the laboratory regarding risk management and quality management (intentions and general guidelines of the laboratory) in accordance with accreditation and regulatory requirements; the objectives of the risk management process taking into account the objectives and strategies of the medical laboratory; analysis of external and internal context; relevant stakeholders identified; formation of the risk management team, coordinated by the person holding the management position, which includes the heads of the departments or their deputies from the organizational structure, with the manager accountable for the risks; job description which assigns responsibilities and authorities to the appropriate levels of the risk management laboratory; necessary resources for risk management; risk indicators selected and lined up with laboratory performance indicators; communicating the inclination toward risk or risk aversion of the medical laboratory (1, 2, 8-12);

Table 1. Example of the template for risk management process planning for the pre-analytical process

RISK MANAGEMENT PROCESS	
RISK MANAGEMENT PROCESS PLANNING - develops the aspects presented in ISO 22367:2020, section 4 (Risk management); and ISO 31000:2018, sections 5 (Framework) and 6 (Risk management process)	
INPUTS	**OUTPUTS**
Forming the risk assessment team: - involvement of people with experience and expertise in the field of risks in their respective fields of interests - involvement of interested persons, internal or external to the medical laboratory - relevant stakeholders: the chairman of the organization, the general manager of the laboratory, the laboratory manager - involvement of executants - department manager * - suppliers: the head of quality assurance, the medical director, collaborating physicians, nurses, biologist **Accreditation and regulatory obligations:** ISO 15189:2012 standard (8) **Procedures, guidelines, and standards adopted by the laboratory:** Procedure for the collecting and processing of blood specimens Procedure for the transport of blood specimens Procedure for patient and sample identification General Data Protection Regulation (GDPR) (14) Normative documentations of the Health Ministry ISO 31000:2018 standard (1) ISO 22367:2020 standard (3) **Description and preparation of the maps:** Pre-analytical process map Processes map Risk management process map	**Risk Management Plan (RMP) adapted to the pre-analytical process, which includes:** Definition of the responsibilities and roles of team members in the job descriptions. Risk evaluation scales: - the scale of the probability of failures occurrence - the scale of severity - the scale of the probability of nonconformity detection - definition of risk categories - the scale of risk exposure Methods and techniques chosen for analysis of risk management: Ishikawa diagram, Pareto diagram, FMEA (3, 4, 38-40), FTA (4, 38, 39, 42) Risk tolerance established by management decision Establishing the risk owner Results assessment guideline Establishing the manner of internal and external reporting of results of the risk management analysis Establishing the person responsible for the implementation and maintenance of the risk management framework Establishing the periodicity of the risk assessment Implementation schedule for the RMP

Note: FMEA - Failure Modes and Effects Analysis, FTA - Fault Tree Analysis, GDPR - General Data Protection Regulation, RMP - Risk Management Plan

* The department manager has knowledge of how to carry out the stages of the testing process and knows the pre-analytical process, ensures that accreditation requirements and customer expectations are met, provides guidance to people involved in the activities of the pre-analytical process.

Identification of processes in the medical laboratory (the process approach):

• Management processes:

1. Laboratory quality policy, quality objectives and description of the quality management elements implemented according to the accreditation requirements of ISO 15189:2012 (8);

2. Internal and external communication process: assigning a responsible person to inform and communicate new national legislative requirements (e.g., normative documentations of the Health Ministry, Public Health Department requirements, General Data Protection Regulation, accreditation requirements); laboratory information management; competence compliance and acknowledgment, and involvement of personnel from all laboratory levels; establishing the ways of communicating results with clinical or critical meaning; establishing the policy for dealing with complaints received from clients regarding the activity of the medical laboratory; releasing the analysis reports; identifying, preparing, analyzing, approving, disseminating, modifying, archiving, and destroying all documents, while specifying the responsibilities of the personnel involved in the document control activity (8, 9, 12-15);

3. Measuring, analyzing, monitoring, and improvement process: identifying the necessity of training the laboratory personnel (both in the professional field and in the management system); planning, conducting, and evaluating training results; systematic and regular analysis of the quality system by the management at the highest level, in order to ensure its adequacy and effectiveness, as well as to introduce necessary changes and improvements; the procedure of resolution of complaints; decisions of improvement (8, 9, 15-17);

• Processes for achieving the product or service:

1. Sourcing process: selection of service providers, equipment, reagents, control materials, calibrators, and supplies that may affect the quality of medical test results; ordering reagents, control materials, calibrators, and supplies; transport follow-up (time) and transport conditions (temperature); ordered product delivery (8, 9,18);

2. Service/ testing result management process: startup of automatic equipment; reagent verification; checking the validity of the calibration and performing the calibration, if applicable; preparation of control materials; verification of the internal control results; receiving the analysis command (for example: biochemical tests); patient identification; sampling of venous blood; transporting and processing samples; receiving and examining samples (7, 8, 18-23);

3. Service/ result release control process: validation of results; identification and control of nonconformities; preventive and corrective actions (1, 8, 9, 17, 24-26);

• Support processes: maintenance process (periodic maintenance of equipment); IT (Information Technology) process; service planning process (electricity and water supply, disposal of biological waste, human and financial resources); internal audit process; staff training process (1, 8, 9, 15, 19, 27);

Schematic representation of the elements of the analyzed process:

A model of representation of the pre-analytical process is shown in Figure 1. The final result/ service is more efficient and effective when its activities and resources are considered as one process. The medical laboratory drafts the worksheet which includes the following information: analyzed process definition and evaluation of objectives and planned targets; related processes; performance objectives and quality indicators of the process; input data of the process; output data of the process; activities (flowchart of the analyzed process); establishing clear responsibilities for the defined process management; identification of the interface between organizational processes; identification of the necessary

resources for process functioning; identification of risks, causes and consequences for clients and all relevant stakeholders; noting opportunities for continuous improvement (1, 2, 4, 8, 9, 17, 28-35).

Establishing the general and specific objectives for the analyzed process (e.g., total testing process):

• The objective is the basis for managerial planning by establishing directions for future action. The objectives must meet the following characteristics in a cumulative manner: specific, measurable, achievable, relevant, time-framed targets. Examples of the general and specific objectives set out in a medical laboratory for the total testing process are given below, but are not limited to them.

• Hierarchy of objectives: general objective and specific objectives

1. general objective (GO): Increase patient safety by implementing a QMS according to the requirements of the ISO 15189:2012 standard;
2. specific objectives (SO):

SO1: improving patient safety through training programs conducted in the first half of 2021 for personnel responsible for recording patient data and information in the laboratory information system (LIS);

SO2: identifying the errors associated with the registration of patient identification data or requested tests in 2021 and comparing the errors with the targets values and results obtained in 2019 and 2020;

SO3: increasing the degree of specialization of nurses from remote collection sites through internal training programs for the purpose of learning and acknowledging the significance of complying with the identification of patient procedures for the collection of blood samples;

SO4: updating the function chart according to the requirements of the laboratory;

SO5: increasing the quality of medical services by decreasing the number of nonconforming samples by 30% in 2021 compared to 2020;

SO6: identifying the possible interferences on biochemical tests (for example: icterus, hemolysis, lipemia) in 2021;

SO7: preventing rejection of samples about to be tested and reporting rejections when they occur (percentage of rejected samples);

SO8: identifying errors associated with inappropriate storage or transport of patient samples;

SO9: identifying errors associated with inappropriate storage or transport of reagents;

SO10: increasing satisfaction of clients' requirements and expectations by 30% in 2021.

Establishing risk management objectives:

• appropriate decision-making after risk management analysis;
• maintaining threats within acceptable limits;
• continuous performance improvement of the medical laboratory.

Established performance indicators and targets for selected objectives

CLSI QMS12-A offers guidelines in selecting and using the quality/ performance indicators in medical laboratories (6). A performance indicator is a quantifiable measure that the medical laboratory uses to determine how well it fulfills operational objectives and established strategies (6). Supplemental Tables 2-5 are not comprehensive, but provide a few examples of indicators selected and monitored in a medical laboratory.

Concepts and ground rules:

• definitions (e.g., risk, risk management, risk source, event, consequence, likelihood/ probability of occurrence, stakeholder, process, specific objective, risk strategy, etc.) (2, 10);
• establishing the criteria for measuring the probability of occurrence and the impact of risks according to the planned objective (32, 36);

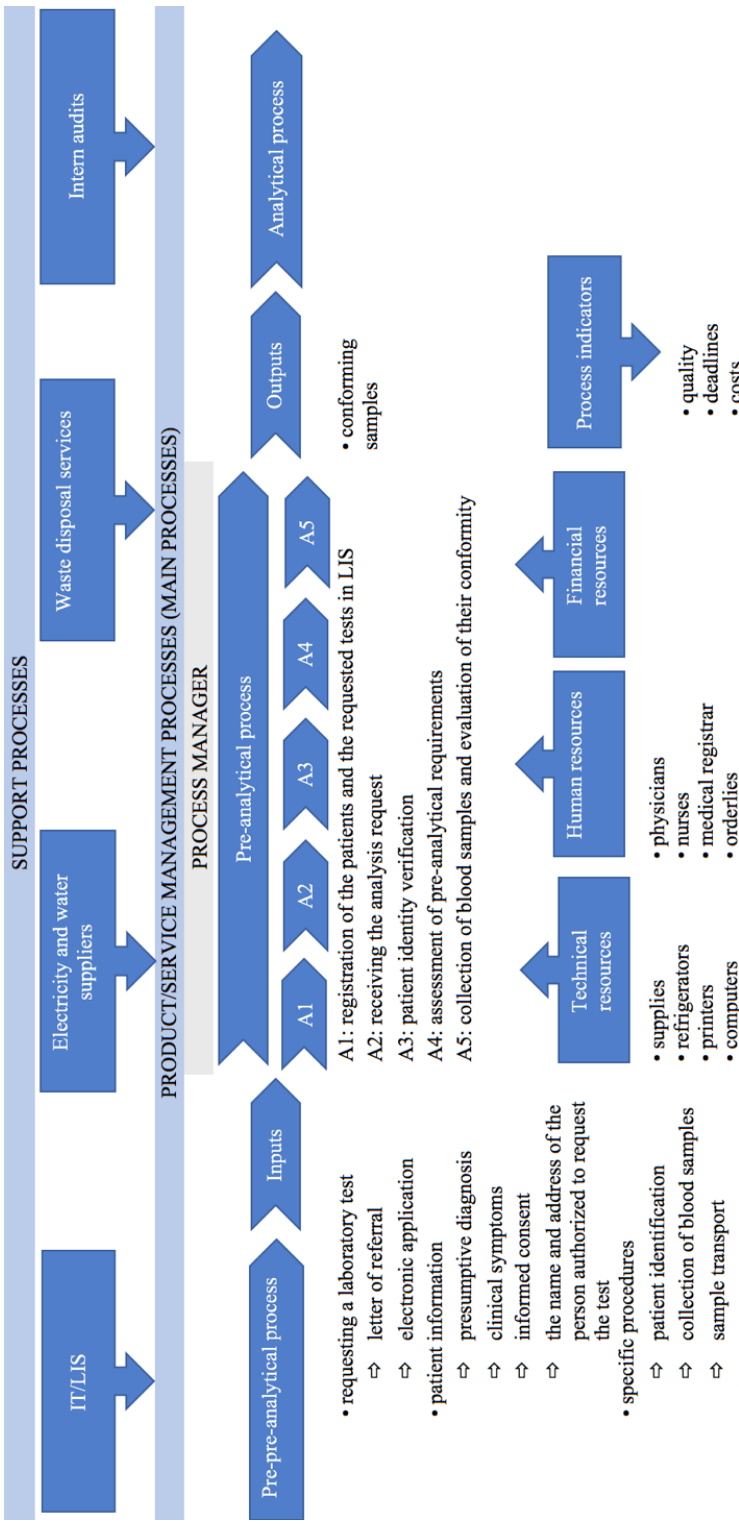

Fig.1. Processes diagram and schematic representation of the pre-analytical process

• risk classification: low, medium, or critical (32, 36);

• The medical laboratory establishes its own scales for the probability of occurrence and for the impact in 5 steps, detailing the risk exposure on a scale of 25 "values". The risk profile obtained is much more analytical, supposing that the risk management is more mature and capable of treating a risk with a risk exposure (occurrence x severity) of "very low-high" differently to a risk with a risk exposure of "high-very low" (32, 36).

• defining risk response strategies:

1. risk acceptance – when the risk exposure is lower than the risk tolerance, it is not necessary to take control measures;
2. risk avoidance – this consists of eliminating activities that generate risks. It must be mentioned that for the medical laboratory, this option was significantly reduced;
3. risk transfer – this includes the participation of a third party in risk management, but it does not mean the elimination of the risk. A contract is concluded (for example: insurance policies) which aims to reduce the risk exposure of the laboratory. However, the laboratory remains accountable to the clients in case a risk occurs (risks associated with the credibility of the laboratory cannot be transferred to a third party);

4. risk mitigation – this is the most frequently used strategy in the medical laboratory, and it aims to reduce the probability of occurrence of the causes of risks and/ or severity of the effects when the risks occur.

• The selection of a risk management strategy is based on comparison of the cost of risk management with the benefits of implementing the strategy, and the cost must be justified and lower than the cost of the consequences that the laboratory would face if the risk occurred.

• techniques and instruments used (including instructions for use and result interpretation guide) (37, 38);

• risk tolerance;

• periodicity and manner of reporting the results of the risk management analysis (for example: annually, whenever necessary meetings are organized to analyze data on new identified risks, or reporting secondary risks of the proposed actions to counteract the inherent risks).

Risk identification

Risk identification is the sub-process that gives the medical laboratory the opportunity to continuously adapt to change, and a permanent character for effective risk management. The medical laboratory can use different techniques to identify risks. ISO 31010:2020 is very general, but it offers a guideline regarding selection and application of different techniques to evaluate risks. CLSI EP18-A2 is a specific standard that is meant to offer guidelines both for the device manufactures, but also for the laboratory managers to identify risks and to develop control strategies for these risks.

Table 2 is an example of a template for the risk identification sub-process for pre-analytical process of the Biochemistry Department in a medical laboratory, which mentions the inputs, tools and techniques used, and outputs of this sub-process.

Most commonly, FMEA (Failure Modes and Effects Analysis), FTA (Fault Tree Analysis), "5 Whys?" and Ishikawa diagram are the risk analysis tools selected and used in a medical laboratory, but they not limited to these. Once selected, it is important that they continue to be used so that the results of the analyses can be interpreted correctly and the measures taken can prove their effectiveness.

FMEA is used to identify potential errors and to determine their effects and causes. In the FMEA table, for each potential error, values are recorded for severity, occurrence probability, and detectability. The control measures are established for the moderate and severe risks, both for the prevention of cause occurrence, but also for the detection of causes of potential errors. Supplemental Tables 6-7 have the format of the working document of FMEA in a medical laboratory.

Despite the advantages, by analyzing each component and creating a list of potential failure modes, the FMEA technique cannot establish relationships between potential failure modes. According to the recommendations of the safety standards, the techniques of FMEA and FTA are used in combination. FTA is a practical analysis for causal analysis of unwanted events, being a top-down analysis.

Risk analysis and evaluation

Risk qualitative analysis is the sub-process in which the qualitative evaluation of identified risks is performed, leading to prioritization according to the severity of effect(s) on the achievement of the proposed objectives. For this analysis, the probability of causes of occurrence scale, the severity of the effects scale and risk exposure scale are used. The risk analysis and evaluation sub-process are shown in Table 3, which is an example of a template for the risk analysis sub-process. The elements contained in the template can be applied and found in each particular analysis for each medical laboratory process.

Table 2. Risk identification for the pre-analytical process

RISK MANAGEMENT PROCESS	
RISK IDENTIFICATION	
- develops the aspects presented in ISO 31000:2018, sections 6.4 (Risk assessment), sub-section 6.4.2, and ISO 22367:2020, section 5 (Risk analysis), sub-sections 5.5-5.7	
INPUTS	**OUTPUTS**
Risk assessment team	**An exhaustive list of risks:**
Analysis of the outputs from other processes:	- includes all risks regardless of their severity
Description of the pre-analytical process	- it is specific to the pre-analytical process
Structure of activities	**Potential effect list**
Planning of activities	**Risk register**
Estimation of duration and costs of activities	**Types of risk:**
Resources plan	Quality risks
Risk Management Plan (RMP)	Management risks
Applying techniques for gathering information and identifying the causes of risks and their effects: Ishikawa diagram, FMEA technique, FTA technique, "5 Whys?" technique	Internal risks
	External risks
	Identification of and establishing risk indicators
Process map or revised process map *	
Information from the literature, databases, published studies	
Historical information	
- previous management review/audit reports	

Note: The elements contained in the template can be applied and found in each particular analysis for each medical laboratory process. * Revised process map is the result of observing deviations from the initial objectives during the monitoring and controlling phase. FMEA - Failure Modes and Effects Analysis, FTA - Fault Tree Analysis

Table 3. Risk analysis and evaluation for the analyzed process

RISK MANAGEMENT PROCESS	
RISK ANALYSIS AND EVALUATION	
- develops the aspects presented in ISO 31000:2018, section 6.4, sub-sections 6.4.3 (Risk analysis) and 6.4.4 (Risk evaluation) and ISO 22367:2020, section 5	
INPUTS	**OUTPUTS**
Risk assessment team	**List of categorized risks in accordance with the probability of occurrence**
Risk register	Pareto analysis was used
Risk management plan (RMP)	**Risk list in accordance to risk exposure**
Risk evaluation scales:	Risk matrix
- scale of the probability of occurrence	Establishment of the risk profile
- scale of severity	**Classification of risks according to the definition of risk categories**
- scale of risk exposure	**Classification of risks according to NPR (Number Priority Risk = O x S x D)**
- scale of probability for nonconformity detection	Priority risk list
- definition of risk categories (critical, medium, low)	Moderate risk list, for further analysis and monitoring
Exhaustive list of risks	
Risk register	**Potential effect list**

Note: D - Detection, O - Occurrence, S - Severity, NPR - Number Priority Risk

Development of the risk response plan

The development of the risk response plan is the sub-process in which the aim is to exploit the opportunities and reduce the threats to which the laboratory is exposed in order to achieve the objectives. For each risk, both the main treatment strategy and a backup treatment strategy are selected.

Risk management means assumed responsibility; the "come what may" attitude is not accepted. For this reason, the achievement of laboratory objectives becomes possible when there exist: a properly designed map of the analyzed process; established internal control measures to keep risk at an acceptable level (preventive actions); measures to be taken if the risk occurs.

An example of a template for designing the risk response plan is shown in Table 4, maintaining the inputs, applied techniques, and outputs.

Risk monitoring, control, and review

Risk monitoring, control, and review is a continuous sub-process. The closely monitored risks are the critical risks, for which additional control measures must be identify, and secondary risks, for which the procedure needs to be revised.

Each identified risk needs control measures for the residual risk to be mitigated up to a clinical acceptable level. Once the residual risk is acceptable, the control measures are included in the "Quality Control Plan". Thus, the establishment of the "Quality Control Plan" is based on risk assessment (7, 42).

Once the risks occurred, the determination of the cause that led to the occurrence of the nonconforming event followed. Risk manifestation represents a nonconformity.

Table 5 is an example of a template for the risk monitoring sub-process for each process in a medical laboratory, in which it mentions the inputs, tools and techniques used, and outputs of this sub-process.

3. A Model of Approach to Risk Management in a medical laboratory

The schematic representation of the risk analysis in a medical laboratory is shown in Figure 2.

Table 4. Risk treatment strategies and risk response plan for the analyzed process

RISK MANAGEMENT PROCESS	
TOLERANCE. RISK TREATMENT. RISK RESPONSE PLAN - develops the aspects presented in ISO 31000:2018, section 6.5 (Risk treatment)	
INPUTS	**OUTPUTS**
Risk assessment team	**Risk response plan**
Risk management plan (RMP)	Each risk identified is a triad "cause–risk–effect" linked to the objective.
Establishing the risk owners	
Risk register updated with all risk characteristics	Responsibilities assigned for risks. Establishing the risk strategies for each risk
Priority risk list	Level of the residual risk accepted
Moderate risk list for further analysis and monitoring	Residual risks list Secondary risks list
Potential effect list	**Backup plan A (contingency plan)**
Risk tolerance established by management decision	Measures taken when the risk occurs Includes activities, budget, managers
Risk treatment options: - avoidance, transfer, mitigation, acceptance	**Backup plan B** Measures applied to the accepted risks if "Plan A" has failed.

Table 5. Risk monitoring and control for the analyzed process

RISK MANAGEMENT PROCESS	
RISK MONITORING, CONTROL AND REVIEW - elaborates the aspects presented in ISO 31000:2018, section 6.6 (Monitoring and analysis) and ISO 22367:2020, section 10 (Risk monitoring, analysis and control activities)	
INPUTS	**OUTPUTS**
Risk assessment team	**Emergency plan**
Risk management plan (RMP)	- previously unplanned measures that will be taken for new risks
- outputs of sub-process planning of risk management process	**Corrective actions**
Risk response plan	**Updates to the risk response plan**
- output of the previous sub-process	- risks that arise will be documented, assessed and withdrawn from the "Risk Register"
List of moderate risks for further analysis and monitoring	**Laboratory's own risk database**
Identification of previously unanalyzed risks	**Updates of risk lists**
Results of performance measurement using quality indicators	**Proposals for changes in the pre-analytical process following changes detected in the risk profile**
Reports of audits	

Through this approach, the answers to the following questions can be found:

What can happen? (Through risk identification)

Risk identification and description is done in relation to the established objectives of the laboratory. Risks do not exist in isolation. For each identified risk, the triad "cause–risk–effects" correlated to the objective is established.

Why? What is the probability of occurrence in the future? What are the consequences?

Risk analysis includes establishing the probability of risk occurrence and the consequences of risks, if it occurred, taking into consideration the presence and efficiency of the existing control measures.

Are there any control measures that can reduce the consequences of risk or probability of occurrence?

Is the risk level acceptable/ tolerable? Is a follow-up risk treatment necessary?

The estimated probability level and estimated impact level are combined to establish the risk level (risk exposure), according to which the risk profile is created. Risk exposure has meaning only in relation to risk tolerance. The limit of risk tolerance is established through comparison of the cost control measures and the cost associated with risk occurrence. Based on the deviation of risk exposure from risk tolerance, decisions are made regarding the magnitude of control measures.

What is the process approach? What is the department approach?

Risk-based thinking is used in the process approach. In most cases, organizations are hierarchically structured on functional departments and led vertically. In this situation, the final client (patient, physician) or any relevant stakeholder is not always visible to all involved in the activities of the organization, and thus the problems that occur at each departmental interface receive a smaller priority than the short-term objectives of the respective departments. Hence, improvements associated with the final client are low or even missing, because the improvement actions are concentrated on the local benefit associated

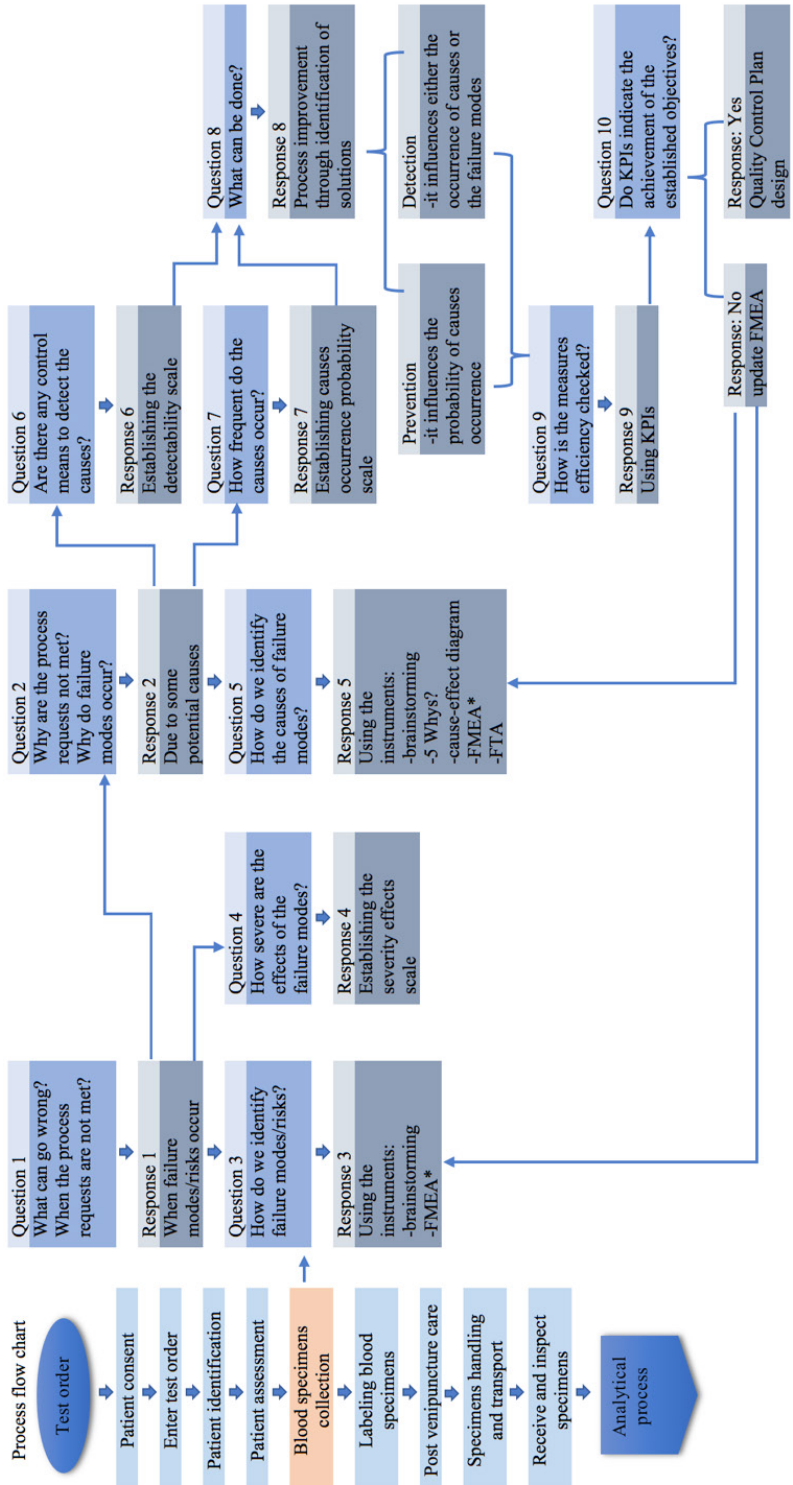

Fig. 2. Risk analysis methodology

with the departmental level function, and not on the organizational global benefit.

In accordance with ISO 9001:2015, the process approach allowed the introduction of horizontal management activities and elimination of barriers between different departments, thus the collective effort was concentrated on the main objectives of the laboratory (9).

The process approach involved systematic definition and management of both processes and interactions, establishing responsibilities for the main actions, measuring the capabilities of the main activities, identifying the interfaces of the main activities from the medical laboratory framework and its functions, focusing on factors that can improve the laboratory activities (resources, methods, materials), and evaluating the impact of risks, consequences, and activities on the clients and other stakeholders.

Can the risk be controlled by the medical laboratory?

Control measures are meant to both lower the probability of occurrence of causes, but also to increase their detectability. From the experience gained in the risk analysis, we recommend

the determination of causes of potential errors using the combination of different tools (e.g., "5 Whys?", FTA); to limit the causes that can be measured using quality indicators, and to avoid as possible, establishing human resource as possible cause.

Assessing the effectiveness of control measures becomes possible when nonconformities are reported by laboratory personnel, both as a way to improve quality and patient safety, and as an opportunity to learn from mistakes ("The only real mistake is the one from which we learn nothing" according to John Powell). Some studies have analyzed the attitude of medical personnel towards nonconformities or incidents or errors encountered (26, 43).

Laboratory personnel have two options for the encountered nonconformity:

• solving the encountered nonconformity and reporting it;

• solving the encountered nonconformity and "forgetting" its existence (43).

The medical laboratory reports the encountered nonconformities that "affect patient safety", according to ISO 15189:2012, section 4.14.6 (8).

The Canadian Patient Safety Institute classifies nonconformities encountered in the laboratory into:

• accidents – events that affect the patient's health, also called "critical incidents", "adverse events" or "sentinel events";

• incidents – events that do not affect the patient's health by diagnostic or therapeutic conduct;

• near-miss – an event that is prevented by detecting it before it could influence the patient's clinical decisions (43).

According to CLSI EP18-A2, near-miss detection must be considered a nonconformity because the probability of detection has been low (4). In medical practice, increased attention is paid to critical incidents in most situations. Franklin et al. note that incident or near-miss reporting could provide more information on opportunities for quality improvement. Some laboratory personnel believe that reporting all types of incidents can lead to filling out too many forms, and they are encouraged to resolve nonconformities and continue their work (43). Jeffs et al. state that this "solve - not report" approach means that the lessons learned are only for the person who solved the nonconformity, and it could become a normality (43).

The presence of persons in the laboratory who "always ask awkward questions" could be the first step in the "solve and report" approach, allowing the dissemination of information, and thus helping several colleagues to solve similar problems.

Conclusions

Risk management ensures that the fundamental requirements for healthy, proactive internal control of the medical laboratory are met.

Acknowledgments

None.

Conflict of interest

None to declare.

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