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Application to Risk Management as Part of the Transition of the Quality Management System from ISO 17025 v2005 to ISO 17025 v2017: Case of MULTILAB Laboratory in Tunisia

Ines Harzli*

Department of Biology, Faculty of Arts and Sciences, Ondokuz Mayıs University, Samsun, 55270, Turkey
*Corresponding author: inesharzli9@gmail.com

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Abstract **Background:** Accreditation ensures a very high level of control of the risks that laboratories may face during their cycle regardless of a systemic situation, internal or external change or even in a state of crisis. MULTILAB, which is an Agri-Food and Environmental analysis laboratory, decided in 2018 to start the project accreditation for the microbiological analysis unit according to the new version of the ISO / CEI 17025: 2017 standard. This study evaluates 3 processes at MULTILAB to identify, evaluate, and control all the risks related to each process using a risk management process. The aim of this study is to reduce the identified risks of the 3 chosen processes in MULTILAB to ensure a complete identification of probable risks to enable then the laboratory to succeed the transition and accreditation project. **Methods:** This study was performed from March to May 2018 in MULTILAB. The samples chosen for the study were 3 processes of MULTILAB; Monitoring and Measurement as a management process, Request Review as realization process and Provision of Skills as a support process. The internal process sheets which include all the data relating to the processes were used to collect data. The risks are defined according to the 5M method and the risk process used comprised 3 phases; identification, assessment and action phase. To evaluate the risks, different rating benchmarks were used for each process. After the definition of the risk's likelihood and severity, the criticality was calculated and then the priority number was defined for all risks. For the action phase, different actions were defined according to the priority level of each risk in each process to reduce or eliminate risks. **Results** : The total number of identified risks was 85 in MULTILAB; Skills Provisioning process had the majority of identified risks (37 risks), Monitoring and Measurement process represented 25 risks and Request Review process had the lowest number of risks (23 risks). Regarding the 5M method, in a total of 3 processes, the highest number of identified risks belongs to the Methods (30 risks) and there are no risks that belong to Machines within MULTILAB. Regarding the treatment priorities, the majority of the identified risks for the three processes were moderate risks. **Conclusion**: A risk management approach is necessary to succeed not just in the accreditation project according to the new version of the ISO17025: 2017 standard but also to succeed in all next projects and to ensure the credibility of the tests carried out. Most of the risks identified do not require immediate action, but permanent control and monitoring can mitigate and even eliminate them completely.

Keywords: *MULTILAB, accreditation, ISO17025: 2017, Risk management*

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1. Introduction

In 2017 as per ISO 17025, the "laboratory is body that performs one or more of the following activities: testing, calibration and sampling, associated with subsequent testing or calibration" [1].

Previously, laboratories were just responsible for carrying out tests in a basic and simple way within a well-defined framework, but currently a test result carried out in one country could be accepted in another country [1].

Actually, more than 60,000 laboratories throughout the world are doing calibration, testing, and sample analysis on a regular basis. Their main purpose is to reassure clients that their results are accurate. It allows them to show that they are technically capable of producing valid and reliable results [2].

The definition of accreditation for a laboratory is the process during which the laboratory's technical competence is assessed, approved and periodically audited

by an internationally recognized authority in accordance with certain standards, for the reliability of the tests and analyzes [3]. At the international level, accreditation is a strong vector of trust facilitating recognition of the reliability of results, as if they had been carried out locally [4].

Laboratory accreditation is an activity which adjusts technical and general requirements based on ISO / IEC 17025 with related accreditation institutions [5]. Accreditation is also an important mechanism to overcome the limited knowledge, budget, planning, policies, and staff needed to improve laboratory services [6].

Accreditation ensures a very high level of control of the risks that laboratories may face during their cycle regardless of a systemic situation, internal or external change or even in a state of crisis. It ensures also the improvement of the organization, the quality of the services or the product it provides, the satisfaction of these customers, a good brand image and staff involvement in a project which creates added value.

Accreditation guaranteed for competent laboratories:

i. Official national and international recognition of the reliability of the results.
ii. Loyal customers with reliable testing, measurement and calibration services that meet their needs.
iii. Become an industry sub-contractor.
iv. To be able to establish itself in a new market given the international recognition.
v. Guaranteed sustainability of laboratory activities.
vi. Receive approval from the public authorities.
vii. Continuously ensure better governance, process and risk management.

In Tunisia, the accreditation of testing and / or calibration laboratories as well as that of technical inspection bodies is based on the principle of voluntary service; it is open to all organizations which request it and which comply with the technical criteria set by the TUNAC (National Accreditation and Quality Council).

The application of ISO/IEC 17025 is a mandatory requirement for obtaining laboratory accreditation. Requirements needed in fulfilling laboratory accreditation by auditing eight elements, namely organization, observation systems, documents, quality system records, relationships with customers and colleagues, laboratory work, quality research, and laboratory personnel [7,8].

In order to obtain laboratory accreditation, MULTILAB was able, thanks to its credible risk management methodology, to retain a certain number of customers throughout the territory of the Republic of Tunisia.

MULTILAB was among the first private Agri-Food and Environmental analysis laboratories to obtain accreditation according to ISO / IEC 17025: 2005 in 2012 and it has succeeded in maintaining ISO / IEC 17025 accreditation following follow-up audits .

Internal audits are carried out each year to verify the accordance of the Quality Management System with the technical requirements of ISO / IEC 17025: 2005 to ensure the effectiveness of the laboratory's activities and management system.

ISO/IEC 17025 as well lets simplify collaboration among laboratories and different associations upon producing larger approbation of findings among nations. Experiment reports and certificates can be regarded as true from one nation to another without the requirement for additional experimenting, which successively enhances international trade [9,10].

ISO 17025: 2005 has been revised by a new version including some modifications (Table 2) [11,12].

The new version appeared in November 2017 updating some concepts. As a result, ISO 17025: 2005 accredited laboratories have to obtain the new accreditation according to the new version by developing their quality management system and integrating

There are 141 requirements of ISO / IEC 17025: 2017 (Table 1).

Table 1. Requirements of standard ISO / CEI 17025: 2017

Requirements of standard ISO / CEI 17025: 2017			
N°	**Chapters N°**	**Requirements N°**	**Number**
4	General requirements	4.1-4.2	2
5	Structural requirements	5.1-5.7	14
6	Resource requirements	6.1-6.6	30
7	Process requirements	7.1-7.11	69
8	Management system requirements	8.1-8.9	26

Table 2. Main modifications in the new edition of ISO/CEI 17025/ 2017

Changes	Description
Change 1	The scope has been reassessed to comprise testing, calibration and sampling linked to subsequent calibration and testing.
Change 2	The process approach now coordinates with more recent standards like ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and ISO/IEC 17021-1 (requirements for audit and certification bodies).
Change 3	The standard possesses now a stronger focus on ITs and includes the usage of computer systems, electronic records and the generation of electronic findings and reports
Change 4	A novel chapter presents the idea of risk-based thinking [12]

ISO/IEC 17025:2017 [13] was modernized cooperatively by ISO and the International Electrotechnical Commission (IEC) under the responsibility of the ISO Committee on conformity assessment (CASCO) [14,15,16].

Currently, analysis and testing laboratories increasingly need to provide their customers with a credible and transparent methodology to give confidence in these results and reduce measurement error.

Accreditation under the ISO17025 standard represents official recognition of the competence of laboratories and enables their clients to find reliable services that meet their needs.

Recognized tests of products from various industries are carried out in accredited testing laboratories to ensure that they comply with legal and customer standards [17].

The issue is that due to different errors that might occur throughout the pre-analytical, analytical, and post-analytic phases, not all laboratory tests will yield conform results [18]. To acquire accurate test findings, error detection must be complete. [19]. The risk is associated with the unknown outcomes of a future event with the assumption that these outcomes will be undesirable [17].

“To deal with it effectively, risk-based considerations must be integrated into an analytical framework such as **Risk Management**” [20].

According to the International Organization for Standardization (ISO) 14971, risk management is described as the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk [21].

Risk management, according to Nichols, is a way of determining relationships in the processes of recognizing, assessing, evaluating, handling, lowering, and continuous monitoring of risks in order to reduce losses and maximize opportunities while keeping risks at an acceptable level. [22].

The Risk Management is comprised in the HLS structure (High Level Structure) of the new versions of management standards (ISO 9001, ISO17025, ISO14001 and others) because today everywhere in the world it is no longer the technical aspect that will be evaluated in companies but the ability of the latter to know the risks in each process of the company and work on the treatment needed to reduce all of risks to ensure a successful management approach. As a result, risk management must be viewed as an integral aspect of an organization's quality management system.

Risk management is currently one of the most popular subjects among management researchers and practitioners [23]. Various risk management strategies were offered in the studies. The risk assessment phase, which includes identification, analysis, and prioritizing, and the control phase, which includes risk management planning, classification, and monitoring, are the two key phases outlined by Boehm [24].

Risk management, according to Kremljak, is a four-phase process that includes planning, evaluation, handling, and monitoring. This procedure corresponds to the Deming cycle of continuous quality management improvement (PDCA - Plan, Do, Check, and Act) [25].

Chapman and Ward have proposed a process consisting of nine phases [26]:

- Defining the project's main features
- Focusing on a strategic risk management approach
- Identifying potential risk locations
- Organization data information about risk assumptions
- Assigning accountability and ownership for a certain risk
- Calculating the degree of uncertainty
- Evaluating and determining the magnitude of the risks
- Assigning responsibility for risk planning, monitoring, and management.

Risk management includes 3 phases:

- Identification of risks
- Assessment of risks
- Mitigation of risks

First, with identifying risks, we register all the potential risks that concern all the laboratory’s activities [27].

The risk can be identified using multiple techniques such as System Mapping Approaches (SMAs), 5M method, structured brainstorming, etc. [28].

The risk assessment and determination of its se is necessary for selection of the appropriate measure that depends on the priority of the risk.

The risk assessment step could be carried out in a variety of ways, such as establishing rating benchmarks to define likelihood and severity levels. The assessment could be conducted also using Failure Mode and Effect Analysis (FMEA). This method of analysis is mainly used in medical, biomedical and educational laboratories, hospitals and even in industries.

For the mitigation of risks, laboratories have to establish quality indicators to apply efficient treatment actions.

Risk management approaches must be integrated into the testing process in areas requiring non-expert personnel, departmental communication, and general collaboration. The entire system must participate in enhancing the overall testing process in accordance with ISO standards [27].

To be able to carry out processes in accordance with ISO norms, appropriate and effective personnel training must be ensured. [29].

As a result, the entire system must be involved in improving the overall testing process, successfully carrying out risk management measures, and bringing better rewards to project performance through increased productivity and reduced threat impact [30].

In a global setting, many countries have implemented risk management for laboratories but the majority of the studies were related to clinical, medical, educational and biomedical laboratories. These studies concerned utmost the safety and security. A study in Kenya presented enhanced training for laboratory staffs on bio-security and bio-safety as highly associated with compliance to bio-risk codes [31].

Another study on risk management in clinical laboratories in Africa found that most laboratories have undeveloped transmission control activities as a result of a lack of awareness, a lack of trained personnel in infection control, inadequate infrastructure, and procurement barriers, all of which result in poor infection control [32,33]. Besides, a study at Qatar University concerned the Risk Management Assessments among students, Staffs, and in educational biomedical laboratories in hematology laboratory and microbiology laboratory. This study showed that chemical and ergonomic hazards account for almost a quarter of the identified hazards in laboratories and it recommended control measure can decrease the severity and the likelihood of identified hazards [34]. However, the studies carried out concerning the risk management at test / calibration laboratories and aiming at a transition or the success of an accreditation project are very rare even at global setting.

In Tunisia, the studies done at test/calibration laboratories were carried out in a global way e.g. the risk management studies related to accreditation projects in many Tunisian laboratories and other bodies were based on a single risk rating benchmark to evaluate likelihood and severity of risks of different processes.

In this study, the rating benchmarks for each process are different from each other given the risks, its levels of probability of occurrence and its levels of severity differ from process to other.

In terms of risk management, MULTILAB executives began to be concerned not only about the risks associated with work accidents, financial losses or the notion of criminal risk but also risks such as customer dissatisfaction, regulatory environment, information systems, IT security, and market competition.

The Quality Management Unit has developed the internal documents necessary for controlling risks relating

to the processes, including process sheets including all the processes data (Risks, input data and output, performance indicators, etc.) to define a benchmark for rating the risks of process (identification, analyzes, evaluation and treatment) to define then control and monitoring plan relating to identified risks. The process sheets can be revised after having carried out continuous monitoring of risks and treatment actions either to reclassify the risks or to completely eliminate the risks treated.

The main objective of this study was to assess the ability of the MULTILAB laboratory to successfully complete the transition to the new version of ISO 17025:2017 standard.

To approach this objective, we identified and evaluated the risks of Monitoring and Measurement process, Request Review process and Provision of Skills process following different models of rating benchmark for monitoring and mitigating risks to decide the measure controls.

2. Methodology

The study was conducted from March to May 2018 at MULTILAB in Tunisia.

3 processes were selected and used, namely Monitoring and Measurement as management process, Request Review as realization process and Provision of Skills as support process.

The processes chosen are of different class since the assessment of the risks relating to the transition to the new version of the standard mainly concerns these 3 processes so they were included to ensure the identification and effective treatment of the identified risks.

The chosen processes are exposed to several types of risks like for example, slow treatment of complaints, no follow-up of deviations, late communication with the customer on corrective actions, customer loss...

The risks identified were defined according to the 5M method (Manpower, Machines, Materials, Methods, Management) to ensure a detailed assessment of the probable risks.

The study was evaluated and then approved by the MULTILAB's Quality Management Unit.

A SWOT analysis was prepared to evaluate the case study method (Figure 1).

To assess risks, risk matrix and different rating benchmarks were used.

a) Risk Assessment Tools

The documents used for assessment included laboratory manual quality, process mapping, processes sheets. The process diagrams have been used to obtain the relative risks according to the 5M method.

b) The Risks Identification and Evaluation

The risk's identification tables of each process contains a description and a classification of risks; the risk's evaluation tables includes an estimation of likelihood, severity, criticality and a prioritization number.

For Monitoring and Measurement, the likelihood and severity had respectively 4 levels, as shown in Table 3 and Table 4.

For Request Review, the likelihood and severity had respectively 4 levels, as shown in Table 5 and Table 6.

For Provision of Skills, the likelihood and severity had respectively 4 levels, as shown in Table 7 and Table 8.

➔ Strenghts	➔ Weaknesses
* Wide range of identified risks. * Detailed definition of risks relating to the process. * Risks identified according to the process diagrams (process activity diagrams). * Identification of different rating reference benchmarks for each process. * A detailed determination of the treatment actions for each risk according to its priority. * A method that shows continuous improvement in the laboratory.	* Data collection based just on process sheets. * Lack of data collected following interviews with laboratory teams or brainstorming sessions.
➔ OPPORTUNITIES	**➔ Threats**
* The development of other risk assessment methods to improve the realism of the business, the image of MULTILAB. * Attract new customers and therefore increase annual turnover. * Increase in analysis requests with diversification of analyzes. * Optimization of the management of risk sources. * Updated vision on changes in risk analysis requirements.	* Loss of data relating to risk assessment and treatment. * Continuous evolution of risk management methods on an international scale. * Insufficient innovation capacity could threaten competitiveness and slow down risk management activities within MULTILAB.

Figure 1. SWOT analysis of the method used for risk assessment

Table 3. Levels of likelihood of risks in the Monitoring and Measurement

Levels	Quoting	Description of levels
Infrequent	1	Once / 2 years
Possible	2	Once / 1 year
Frequent	3	Once / 6 months
Very frequent	4	Once / 3 months

Table 4. Risk severity levels in the Monitoring and Measurement process

Levels	Quoting	Description of levels
Weak	1	No significant impact on MULTILAB
Mean	2	A more or less significant impact with performance degradation within MULTILAB
Serious	3	A significant impact that puts MULTILAB's reputation at stake
Very serious	4	A serious impact on customer relations and brand image

Table 5. Levels of likelihood of risks in the Request Review process

Levels	Quoting	Description of levels
Reasonably impossible	1	Once / 1 year
Rarely possible	2	Once / 6 months
Possible	3	Once / 3 months
Very possible	4	Once / month

Table 6. Risk severity levels in the Request Review process

Levels	Quoting	Definition of levels
Disturbing	1	Negligible impact on customer satisfaction
Relatively serious	2	Indirect impact on customer satisfaction
Really serious	3	Financial loss
Unacceptable	4	Customer loss

Table 7. Levels of likelihood of risks in the Skills Provision process

Levels	Quoting	Definition of levels
Impossible	1	Once / 6 months
Unusual	2	Once / 3 months
Frequent	3	Once / month
Very fréquent	4	Once or more times / month

Table 8. Risk severity levels in the Skills Provision process

Levels	Quoting	Definition of levels
Benign	1	No impact on the performance of activities
Serious	2	Low impact on the realization of activities
Important	3	Significant impact on the performance of activities
Major	4	Serious impact on the implementation of activities

Regarding the risk evaluation, criticality levels for risks were calculated separately by multiplying the likelihoods and the severity scores of risks.

$$Risk\ Criticality(Cr) = Likelihood\ \mathbf{X}\ Severity$$

Then a risk matrix was defined as shown in Figure 2.

According to the priority level of the risks; the risks have been divided into 4 levels; critical risks (priority 1), high risk (priority 2), moderate risks (priority 3) and minor risks (priority 4) as shown in Table 9. Each level was described as shown in Table 10 and Table 11.

Table 9. Risk treatment priority grid

Rating	Risk levels	Descriptions
Cr≤3	Minor	Follow up without actions
4≤Cr<8	Moderate	To be continuously monitored
8≤Cr<12	High	Programming of actions to reduce or eliminate the cause of the risk
Cr≥12	Critical	Immediate treatment action

***Cr:** Criticality.

Table 10. Risk levels descriptions

Risk levels	Significations	Rating level
Minor	Low impact on the company's activities: • Minor impact on analytical and financial activity. • Does not impact the brand image	Cr≤3 Limited risk to control
Moderate	Moderate impact on the company's activities: • Non-serious disruptions on analytical and financial activity • Moderate impact on brand image	4≤Cr<8 Acceptable risk and to follow up
High	Serious impact on the normal functioning of the company: • Disruptions for a few days affecting activities. • Quite significant impact on the financial situation and brand image.	8≤Cr<12 Significant risk to be reduced
Critical	Very serious impact on the company's activities: • Financial loss • Loss of customer	Cr≥12 Unacceptable risk to prioritize

*Cr: Criticality.

Table 11. Classification of risks according to their priorities

Priority levels	Critical Risks (Priority 1)	High Risks (Priority 2)	Moderate Risks (Priority 3)	Minor Risks (Priority 4)
Identified risks	--	--	--	--
Total	--	--	--	--

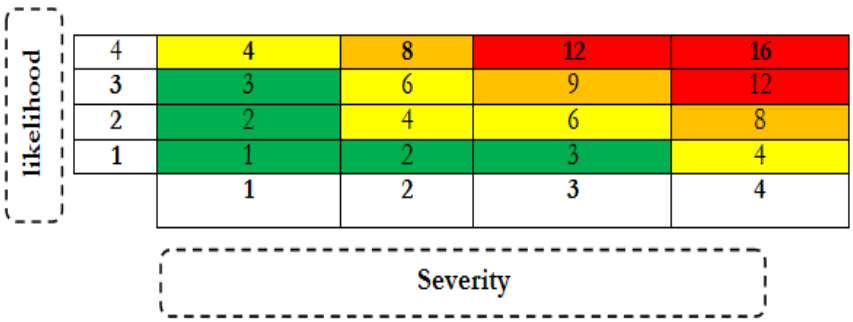

Figure 2. Criticality matrix

Afterwards, treatment actions relating to the various identified risks were defined to propose them to the managers of the different units and also to the managers of the laboratories to approve it.

c) Statiscal Analysis

The data from the processes sheets, which was utilized to evaluate risks, was transferred to the computer for analysis using Microsoft Office for Windows 10 (version 21H1).

The data in this study are descriptive of the risks and controls.

The Microsoft Word 2010 was used to draw graphs and figures.

The Radar graph was used to assess the criticality of the risks identified for each process.

The Histogram chart was used to present the distribution of risks for the three processes studied.

3. Results

a) Distribution of risks for the 3 processes

i. Identification and assessment of the risks

The different risks of each process, its frequencies, severity and levels were defined respectively.

For Monitoring and Measurement process the total defined number of risks was about 25 risks as shown in Table 12.

Table 12. Identification and risk assessment of the Monitoring and Measurement process

Risks	Rating						Ranking
	F	S	Criticality				
• Management *Absence of sending of acknowledgment after receipt of customer complaint.	3	1					R3
• Management *Communication in delay on the corrective actions decided	2	3					R13
• Methods *Discrepancy declared not recorded on observation of discrepancy.	1	3					R4
• Methods *Poor assessment of the impact of deviation	2	3					R14
• Management *Absence of follow-up of the variations on the repertoires.	2	2					R8
• Methods *Low complaints handling.	1	3					R5
• Materials *Lack of meeting reports (collaboration to identify the causes of the discrepancy).	2	1					R1
• Management *Deviation tracking is not applied within the set deadlines.	3	3					R21
• Management *Lack of communication with the customer on corrective actions.	2	3					R15
• Management *Lack of evaluation of the effectiveness of the actions decided.	2	3					R16
• Management *Evaluation carried out outside the set deadlines.	3	3					R23
• Methods *Repetitive deviation.	3	4					R24
• Materials *Ineffective means of evaluation.	3	3					R22
• Methods *Lack of recording of overruns, evaluation of the effectiveness of corrective actions.	2	2					R9
• Manpower *No transmission or late transmission to the auditor of the reference documents.	1	2					R2
• Management *Communication of delays on audit plans	1	3					R6
• Management *Non-availability of auditors	2	3					R17
• Management *Poor planning of audit programs.	1	3					R7
• Methods *Scheduled audits inconsistent with the objectives.	1	4					R10
• Materials *Lack of budget allocated to annual audits.	3	4					R25
• Management *Lack of impartiality of the auditor.	1	4					R11
• Methods *Methodology carried out not in accordance with that planned and validated during programming.	1	4					R12
• Methods *Lack of presentation of one of the points at the opening meeting.	2	3					R18
• Materials *Lack of review and confirmations of discrepancies at closing.	2	4					R19
• Management *Audit discrepancies not kept and disseminated to managers.	2	4					R20

For Requests Review process, the total defined number of risks was about 23 risks as shown in Table 15.

For Skills Provision process, the total defined number of risks was about 37 risks as shown in Table 18.

ii. Interpretation of process risk assessment

After identifying, characterizing, defining the criticality and also prioritizing the potential risks to the processes.

We illustrated the different levels of risk criticality of the 3 processes with radar graphs as shown in Figure 6 – Figure 8.

b) The Risk Assessment of processes risks

i. The Risk Matrix

The defined risks matrix were defined for each process as shown in Figure 3 – Figure 5.

ii. The Assessment of Risks Priorities

The Risk Priority is the result of combining the likelihood and the severity of a risk.

For Monitoring and Measurement process, the assessment of risks priority of identified risks presented 2 critical risks, 5 high risks, 11 moderate risks and 7 minor risks as shown in Table 13.

For Requests Review process, the assessment of risks priority of identified risks presented 2 critical risks, 6 high risks, 9 moderate risks and 6 minor risks as shown in Table 16.

For Skills Provision process, the assessment of risks priority of identified risks presented 1 critical risk, 4 high risks, 20 moderate risks and 11 minor risks as shown in Table 19.

After identifying, characterizing, defining the criticality and prioritizing the potential risks to the process the different levels of risks criticality of each process as shown in Figure 6 - Figure 8.

c) Recommended Control Measures

According to the different risk priorities of each process, lists of actions proposed to mitigate or eliminate the risks have been defined as shown in Table 14, Table 17 and Table 20.

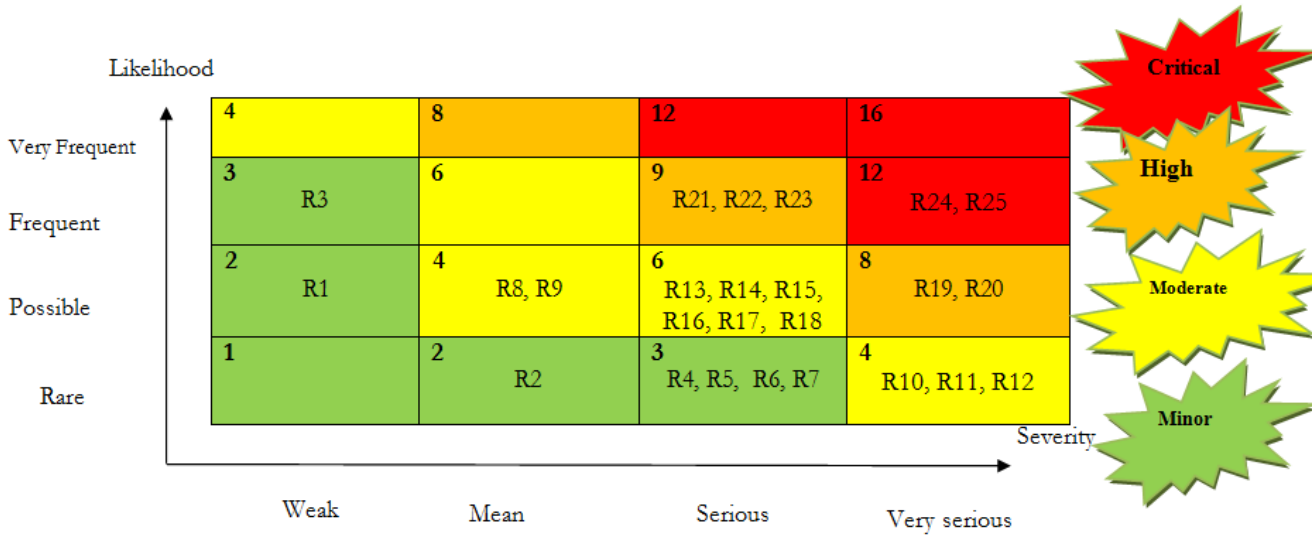

Figure 3. Risk matrix of Monitoring and Measurement process

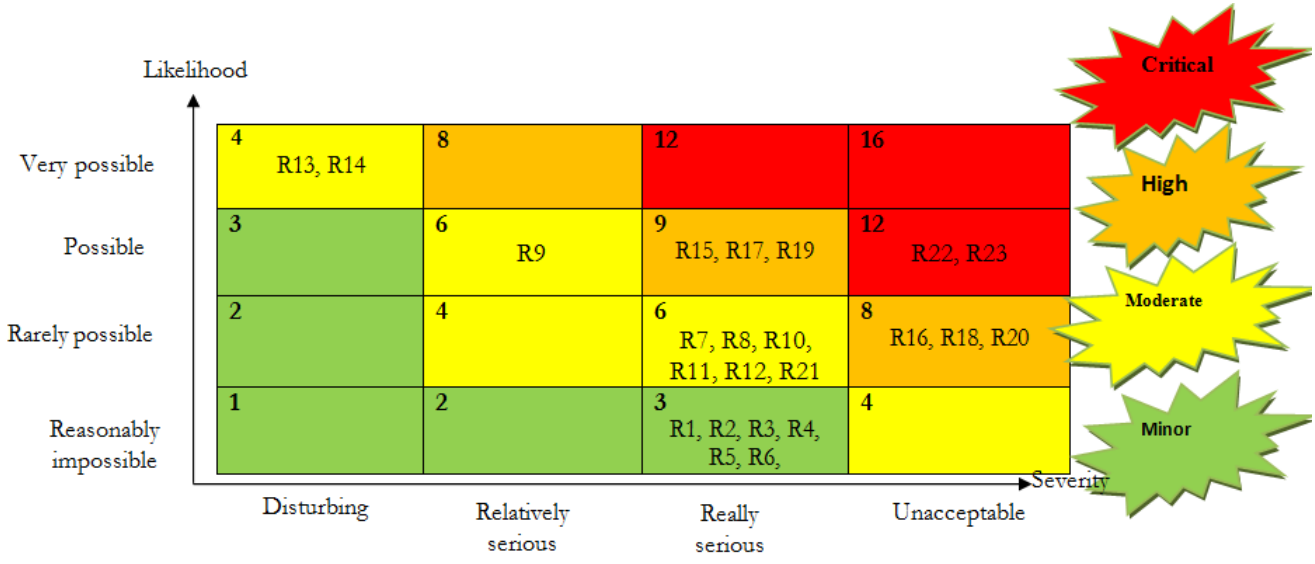

Figure 4. Risk matrix of the Request Review process

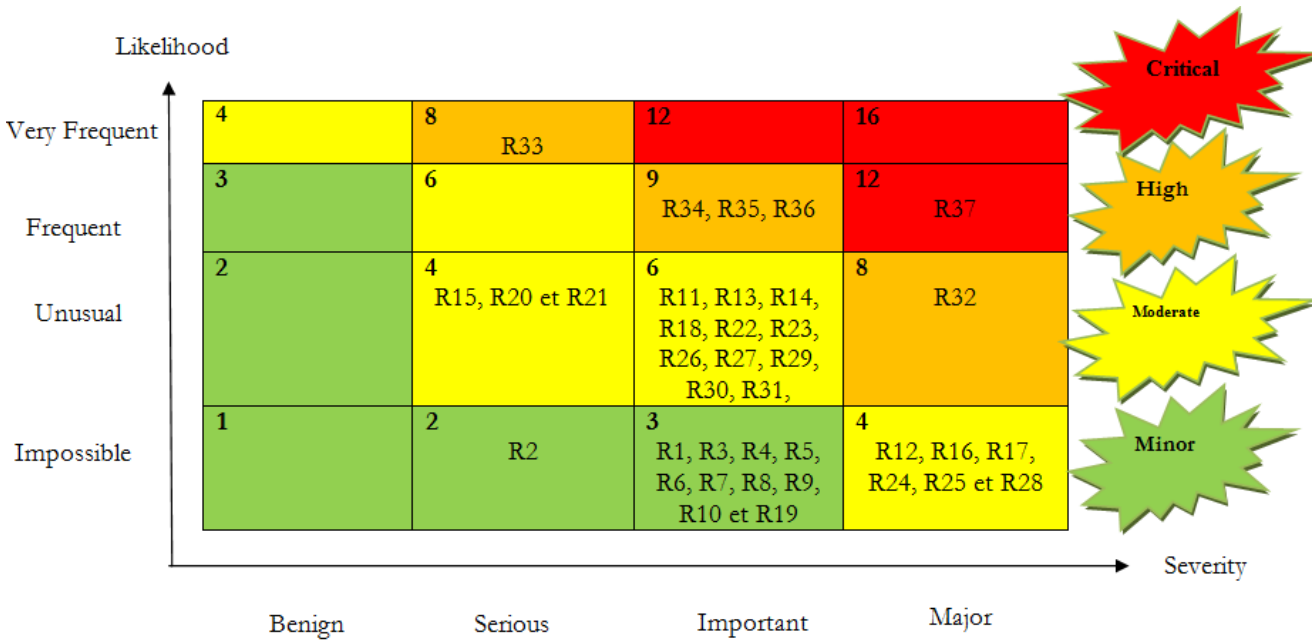

Figure 5. Risk matrix of the Skills Provision process

Table 13. Risks classification of the Monitoring and Measurement process

Priority levels	Critical Risks (Priority 1)	High Risks (Priority 2)	Moderate Risks (Priority 3)	Minor Risks (Priority 4)
Identified Risks	R24 et R25	R19, R20, R21, R22, R23	R8, R9, R10, 11 R12, R13, R14, R15, R16, R17, R18	R1, R2, R3, R4, R5, R6, R7
Total	2	5	11	7

Table 14. Proposed actions to control the risks of the Monitoring and Measurement process

N°	Risk Priorities	Proposed actions
R1	2	Record all the details of the identification of the causes of deviations in a report to ensure the traceability of the actions / responsibilities set.
R2	2	Set a date when scheduling audits to send reference documents
R3	3	Set an obligation to return an acknowledgment of complaint to a customer
R4	3	Immediate recording of any discrepancy on the recording medium
R5	3	Staff awareness of the need for vigilant treatment of any deviation / complaint
R6	3	Set a date to send the audit plans to the auditors
R7	3	Ensure an effective methodology for planning audits
R8	4	Make staff aware of the need for periodic monitoring of recorded deviations.
R9	4	Ensure traceability of any modification to deviation processing times.
R10	4	When scheduling audits, ensure consistency with the laboratory's annual strategy as well as with the objectives in the event of a project or change.
R11	4	Ensure a rigorous evaluation and follow-up of the actions taken by the auditor during the audit
R12	4	Continuous monitoring during the compliance audit of the methodology set.
R13	6	Set an obligation to transmit the deviation to the RMQ on a fixed date for a better analysis of the deviations and definition of treatment actions.
R14	6	Ensure collaboration between those involved in deviation treatment to effectively analyze any potential consequences.
R15	6	Immediate communication with the client on the treatment actions decided.
R16	6	Schedule a periodic meeting to assess the deviation treatment actions until the deviation is closed.
R17	6	Communication with several auditors before setting the annual program to ensure the availability of the selected auditors.
R18	6	Presentation of all the points of the audit program one by one during the opening meeting.
R19	8	Ensure the confirmation of audit discrepancies with the auditor before launching the processing procedure.
R20	8	Ensure the immediate recording of audit discrepancies and have them communicated to managers.
R21	9	Set up periodic meetings to monitor the progress of treatment and to close the differences treated.
R22	9	Optimization of the choice of means set to effectively assess corrective actions.
R23	9	Raise awareness among those concerned by the evaluation of actions to deal with deviations on meeting deadlines to avoid serious consequences.
R24	12	Set and monitor an annual budget from the start of the year for audits.
R25	12	Return to the impact study and the causes of any repetitive deviations to decide again on its treatment.

Table 15. Identification and risk assessment of the Request Review process

Risks	Rating						Ranking
	F	S	Criticality				
• **Manpower** * Customer request not transformed into request form	1	3					R1
• **Manpower** *Lack of data verification with technical managers	1	3					R2
• **Manpower** *Commercial lack of sales representatives to receive customer requests	2	3					R7
• **Methods** *No request for reformulation of requirements	1	3					R3
• **Methods** *Exceeding the deadline for feedback of feasibility information to customers.	2	3					R8
• **Methods** *Application received incomplete	3	3					R15
• **Materials** *Non-functional request reception means (power cut).	3	2					R9
• **Manpower** *Unregistered support.	1	3					R4
• **Methods** *Deviations detected but not recorded.	1	3					R5
• **Manpower** *Lack of staff to negotiate requests.	2	3					R10
• **Methods** *Delayed negotiation with the client.	1	3					R6
• **Methods** *Customer Loss.	3	4					R22
• **Materials** *Lack of negotiation with client.	2	4					R16
• **Materials** *Equipment broken down, hence refusal of request.	3	3					R17
• **Materials** * Undocumented feasibility study.	2	3					R11
• **Methods** *Lack of personnel for identification of samples received.	2	3					R12
• **Methods** *Delayed retransmission of non-compliance of the order received.	2	4					R18
• **Methods** *Order acceptance without pre-established agreement.	1	4					R13
• **Methods** *Order received not in accordance with an agreement.	3	3					R19
• **Methods** *Samples submitted for analysis without pre-established agreement (correction).	1	4					R14
• **Methods** *Inadequate amount of samples received with the analysis.	2	4					R20
• **Materials** *Inadequate condition for storing samples.	3	4					R23
• **Methods** *Request not integrated into the customer base.	2	3					R21

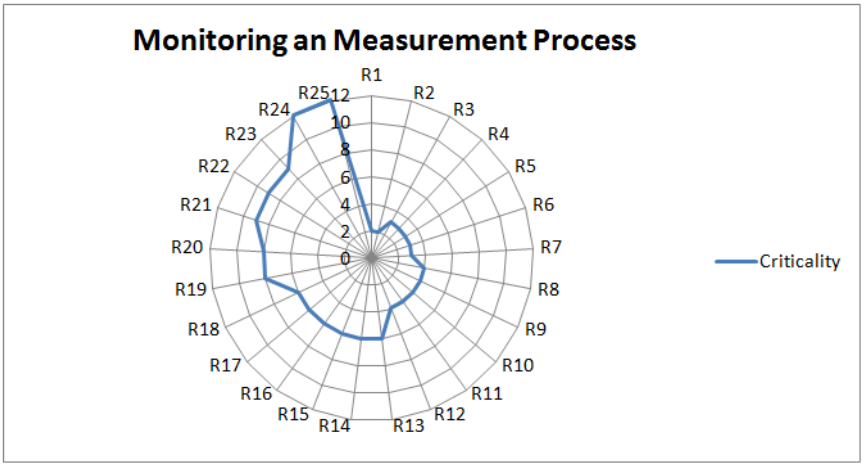

Figure 6. Risk criticality radar for the Monitoring and Measurement process

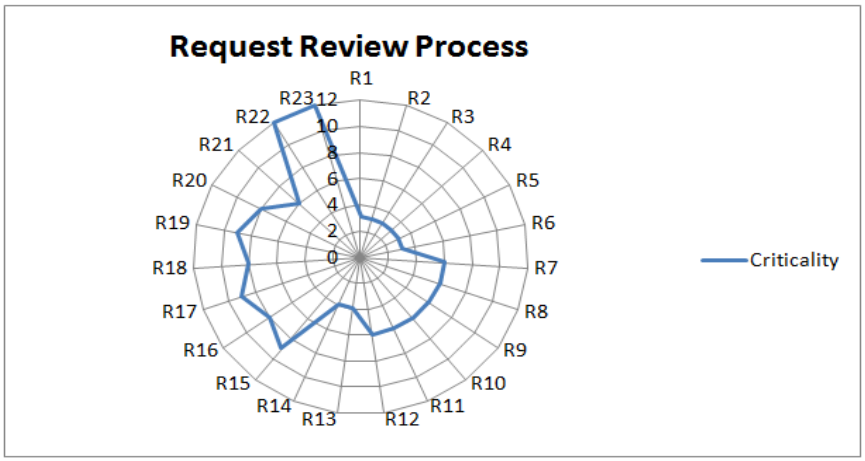

Figure 7. Risk criticality radar for the Request Review process

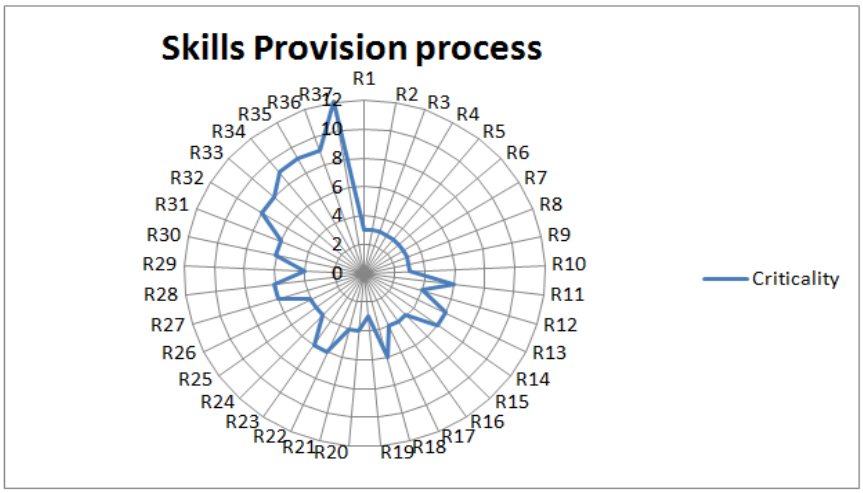

Figure 8. Risk criticality radar for the Skills Provision process

Table 16. Risks classification of the Request Review process

Priority Levels	Critival Risks (Priority 1)	High Risks (Priority 2)	Moderate Risks (Priority 3)	Minor Risks (Priority 4)
Risques identifiés	R22, R23	R15, R16, R17, 18, R19 et R20	R7, R8, R9, R10, R11, R12, R13, R14 et R21	R1, R2, R3, R4, R5, et R6
Total	**2**	**6**	**9**	**6**

Table 17. Proposed actions to control the risks of the Request Review process

N°	Risk Priorities	Proposed Actions
R1	3	Ensure immediate transformation of any request received into a request form.
R2	3	Communicate the technical managers before taking charge of the request.
R3	3	Any reformulation of the requirements with the client must be preceded by a request.
R4	2	Ensure traceability by recording the handling of requests.
R5	2	Ensure any discrepancies detected in the requests received.
R6	3	Ensure speed of action to negotiate the request with the customer.
R7	6	Start recruiting salespeople.
R8	6	Setting of deadlines for communication with the client on the feasibility result.
R9	6	Anticipate possible cuts with the installation of electricity generators.
R10	6	Recruit new staff to assign responsibility for negotiating with the client.
R11	6	Ensure the documentation and recording of any feasibility study completed and communicated to the client.
R12	6	Staff recruitment for the order reception post.
R13	4	Ensure receipt of orders only after an agreement has been established with the customer.
R14	4	Ensure establishment ‘agreement before registering samples for analysis.
R15	9	Ensure that the request is complete before taking charge.
R16	8	Ensure and record all negotiations before the feasibility study.
R17	9	Preventive maintenance.
R18	8	Immediate communication with the client after the results of the feasibility study.
R19	9	Refuse and do not record any order that does not comply with the request.
R20	8	Analysis of the order and the samples received before recording them.
R21	6	Immediately integrate any request on the customer base.
R22	12	Satisfy customers (deadline compliance, impartiality of feasibility analysis, confidentiality ...).
R23	12	Preventive maintenance of sample storage equipment.

Table 18. Identification and risk assessment of the Skills Provision process

Risks	Rating						Ranking
	F	S	Criticality				
• **Manpower** * Wrong definition of the skills management strategy.	1	3					R1
• **Methods** * Poorly expressed skill needs.	2	3					R11
• **Manpower** * Needs expressed inconsistent with the development strategy.	1	4					R12
• **Manpower** * Needs requested and validated not recorded.	2	4					R32
• **Manpower** * Validation of recruits not suited to the needs	1	3					R2
• **Manpower** * Recruitment planning only when skills depart.	2	3					R13
• **Manpower** * Recruitment planned not carried out.	2	3					R14
• **Manpower** * Planned recruitment made late.	2	2					R15
• **Methods** * Discrimination practices during interviews.	1	4					R16
• **Methods** * Ignorance of psychological tests during interviews.	1	4					R17
• **Management** * Ignorance of the social climate when planning interviews (date, level recruited, location).	4	2					R33
• **Material** * Incomplete registered job profile sheet.	2	3					R18
• **Material** * Individual skill sheet incomplete.	3	3					R34
• **Management** * Skills not integrated.	1	3					R19
• **Manpower** * Departure of skills without notice.	3	4					R37
• **Manpower** * Authorization carried out without planning.	1	2					R3
• **Management** * Poor career management, especially key skills.	3	3					R35
• **Management** * Short integration period.	1	3					R4
• **Management** * No follow-up of personal files.	2	2					R20
• **Manpower** * Authorization carried out not registered.	2	2					R21
• **Methods** * Organizational chart not updated.	2	3					R22
• **Management** * Lack of a sense of impartiality when expressing training needs	1	3					R5
• **Manpower** * Lack of coordination between management and laboratory management when expressing training needs.	2	3					R23
• **Methods** * Budget applied without validation	1	3					R6
• **Methods** * Excess of validated training inconsistent with the laboratory strategy	1	4					R24
• **Methods** * Underestimation of the annual training budget.	1	3					R7
• **Management** * Lack of annual training budget.	1	4					R25
• **Manpower** * Incomplete registered training request.	1	3					R8
• **Manpower** * Absenteeism of the trainer during training.	2	3					R26
• **Manpower** * Poor communication between the manager and the staff to be trained (date and content of training).	2	3					R27
• **Manpower** * Lack of professionalism of the chosen trainer.	1	4					R28
• **Management** * Lack of staff motivation for training.	3	3					R36
• **Methods** * Poor management of training (duration and responsibilities of staff).	2	3					R29
• **Methods** * Lack of follow-up of the training program.	1	3					R30

Risks	Rating						Ranking
	F	S	Criticality				
• **Materials** * Lack of rigorous evaluation of trainers.	1	3					R9
• **Manpower** * Lack of explanatory support to follow the training.	2	3					R31
• **Manpower** * Efficiency evaluation sheet not recorded.	1	3					R10

Table 19. Risks classification of the Skills Provision process

Priority levels	Critical Risks (Priority 1)	High Risks (Priority 2)	Moderate Risks (Priority 3)	Minor Risks (Prioritéy 4)
Risques identifiés	R37	R32, R33, R34 et R36	R11, R12, R13, R14, R15, R16, R17, R18, R20, R21, R22, R23, R24, R25, R26, R27, R28, R29, R30 et R31	R1, R2, R3, R4, R5, et R6, R7, R8, R9, R10 et R19
Total	**1**	**4**	**20**	**11**

Table 20. Proposed actions to control the risks of the Skills Provision process

N°	Risk Priorities	Proposed Actions
R1	3	Set an effective strategy suitable for any revision to manage MLTILAB skills.
R2	3	Recruit and validate skills only in line with the requested needs.
R3	2	Establish an annual plan of the authorizations to be carried out.
R4	3	Set an integration period ranging from one to two years for new recruits.
R5	3	Ensure rigorous validation of expressed skills needs.
R6	3	Collaborate between MULTILAB managers to validate the annual skills management budget.
R7	3	Accentuate budget studies to properly estimate annual expenditure in terms of skills management.
R8	3	Check the completeness of training requests sent to the Quality Management Manager.
R9	3	Periodic review of the criteria and the scoring grid for trainers.
R10	3	Ensure the recording of any evaluation file of the effectiveness of the training carried out.
R11	6	Sensitize managers on the right rules and ways of expressing skills needs.
R12	4	Communicate MULTILAB's strategy in terms of skills management to managers.
R13	6	Establish an obligation to give notice of departure in resource contracts.
R14	6	Set fixed deadlines for carrying out each scheduled maintenance.
R15	4	Set fixed deadlines for carrying out each scheduled maintenance.
R16	4	Make officials aware of any act of discrimination prohibited during interviews.
R17	4	Sensitize managers on the application of a test during interviews.
R18	6	Ensure the completeness of any job description before registration.
R19	3	Comply with the procedure for integrating new skills recruited.
R20	4	Periodic follow-up of personal files.
R21	4	Immediately record any authorization file made.
R22	6	Ensure a periodic review of the organization chart in the event of departure, promotion and others.
R23	6	Set up meetings between management and managers to discuss expressed training needs.
R24	4	Set a number of annual training sessions according to MULTILAB's strategy and objectives.
R25	4	Plan and validate an annual budget for training.
R26	6	Extend training programs to have several trainers available at the same time.
R27	6	Communicate to the personnel to be formed the date and the training program as soon as it is fixed with the MULTILAB management and the trainer.
R28	4	Perform a rigorous evaluation of trainers to ensure the smooth running and achievement of the training objectives.
R29	6	Determination of the duration and content of training after evaluation of the availability of personnel to be trained.
R30	6	Ensure a follow-up sheet to notify any deviation during the training.
R31	6	Inform the trainer on the preparation of support to be provided to the trained personnel.
R32	8	Ensure the recording on paper and on the network of any validated training needs.
R33	8	Periodic review of the external and internal context before any recruitment planning.
R34	9	Periodic review of individual skills sheet data
R35	9	Establish a management strategy for former MULTILAB skills.
R36	9	Ensure staff motivation means during training.
R37	12	Ensure a close notice in the contract when recruiting.

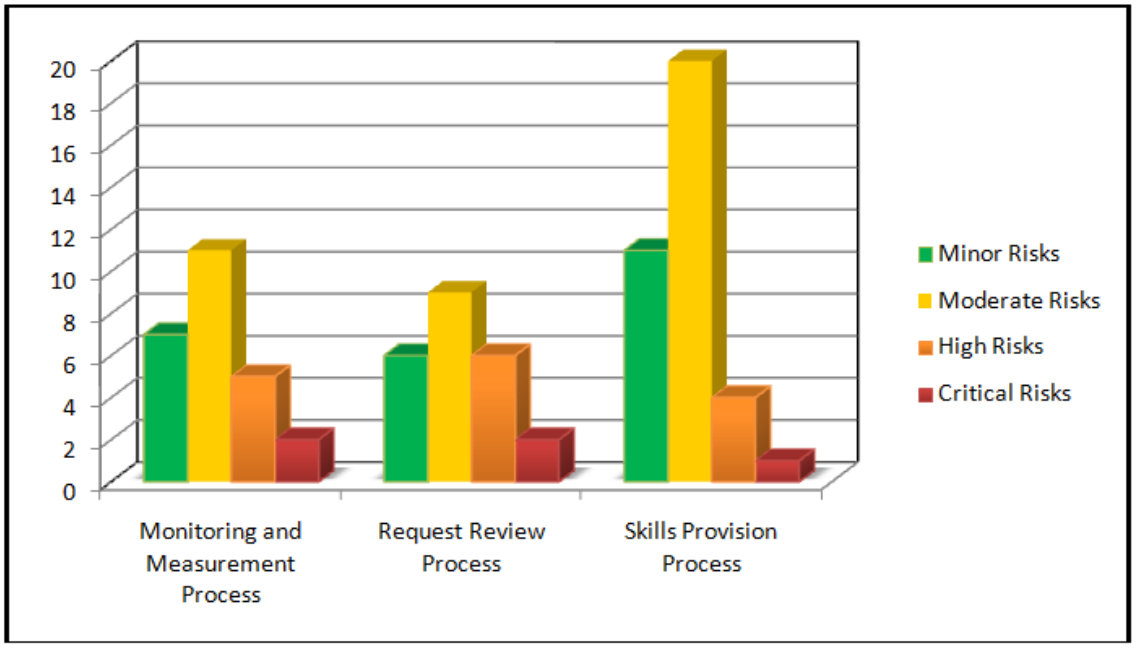

Figure 9. Distribution of risk levels by process

4. Discussion

Given the globalization of trade today, concern for the environment, health and consumer protection is still very high. As a result, standard-setting, certification, accreditation and conformity assessment bodies have set the assessment bar at a very high level to achieve compliant products and services, to improve the international competitive environment by minimizing obstacles and by application of the requirements relating to risk control and for the protection of the environment and consumer health.

The accreditation of Agri-food and environmental analysis laboratories will allow them to meet the requirements of customers concerned about the safety of the products they commonly consume and of industrialists concerned with offering the market safe products that comply with international requirements and according to customers' requirements.

The issue for these laboratories is that they are unable to accomplish and guarantee successful test findings due to a variety of risks that may arise during various process phases. Therefore, including the Including the notion of risks in any phase of the process as well as in the process sheets will make it possible to permanently and continuously identify, assess and control any probable risk to ensure its mitigation or its elimination.

A study carried out by Vasilnakova (2018) concluded that the implementation of a breast risk management process in all the activities of calibration / test laboratories is in high demand to minimize the appearance of risk as much as possible and therefore reduce its impact on activities the laboratory processes [16].

Laboratories that can successfully detect and assess risks will be better able to increase their chances of gaining accreditation by proving their technical competence and ability to produce valid and reliable results [16].

The present study aims to assess the risks encountered in three different types of MULTILAB laboratory processes; Monitoring and Measurement process as a Management process, Requests Review process as a Realization process and Skills Provision process as Support process.

The study concluded the criticality of identified risks and actions or control measures proposed to mitigate or reduce risks.

The current study's findings revealed two significant findings. First, for the 3 processes different risk number was identified; Skills Provision process had the highest number of risks (37), Requests Review process had the lowest risks number (23 risks) and Monitoring and Measurement process had 25 risks (Figure 9). Second, the majority of the identified risks were of moderate priority. In details, for Skills Provision process, there was only 1 critical risk. However, for Monitoring and Measurement process and for Requests Review process there were 2 critical risks. Thus, the laboratory has to focus first on the application of actions and constant monitoring to reduce the severity of moderate risks which presented the highest number and at the same time it needs to determine treatment actions to eliminate critical risks.

The current study’s findings demonstrated also that the total number of risks related to the methods is equal to 30, the risks related to the manpower were about 24, those related to the management, were about 20 risks and finally there were 11 risks related to materials and no risks related to machines were identified.

Thus, the laboratory’s Quality Management Unit needs to focus on creating a risk management process and to include it into the process mapping of the laboratory to facilitate the process of risk management within all activities.

Studies have highlighted the importance of risk management as a well-defined laboratory process. For example for agri-food laboratories, Tummala and Schoenherr (2011) introduced a supply chain risk management process to help laboratory managers to identify, assess and control risks in the performance of the supply Chain [35].

Another study done by Leat and Revoredo-Giha (2013) conducted that it is true that the focus on risk management seems to be one of the difficult responsibilities of managers, but it is necessary to have a high perception to anticipate and identify risks in order to manage them accordingly [36].

5. Limitations

This study's main limitation is the small sample size (only 3 processes) and the data used for risk identification comprised only process's sheets so this could compromise the results.

In addition, this study did not cover a detailed statistical analysis, thus a permanent follow of risks and control measures related to a statistical analysis should be done to create an efficient risk management process.

6. Conclusion

ISO / IEC 17025 and which defines a series of general requirements relating to the competence of testing and calibration laboratories. It enables laboratories to gain international recognition and provide reliable test results, which allows it to improve its image and consolidate its competitive position in the market.

Accreditation according to the ISO17025 standard represents official recognition of the competence of conformity assessment bodies (testing or calibration laboratories, inspection or certification body, etc.) and allows their client to find reliable services that meet their needs. In order to maintain this recognition, these bodies must regularly submit to periodic re-evaluations carried out by the accreditation body, which thus checks whether they remain in compliance with the requirements in this area and ensures that they comply with their work standards.

This study is the first attempt to assess the risks encountered in agro-food analysis laboratories aiming to be accredited according to the new version of the ISO / IEC 17025/2017 standard.

The data obtained highlighted the risks relating to the various processes chosen as well as the measures adopted to manage the risks. The results are used as a basic tool to improve the quality of the activities of the MULTILAB laboratory to successfully transition the Quality Management System to the new version of the ISO 17025: 2017 standard.

This study showed that most of the risks identified are related to laboratory methods and that the highest number of risks relates to the Skills Provision process.

7. Recommendations

In the future, based on the results of this study, the quality management unit should focus on setting up a risk management process to integrate it into the risk mapping, generate a complete database on the risks relating to the various processes as well as their follow-up actions. It must also establish a plan to recruit qualified personnel in the field of risk management.

In particular, it is necessary to plan awareness-raising sessions for all laboratory units.

8. Prospective

Further additional studies should be performed in the laboratory to further emphasize the need for the integration of the risk management process. For example, research should be conducted to study the risks of other laboratory processes to create aggregate data on the likely risks, its severity and likelihood levels. So in this way, the sample size is going to be enlarged and as well the monitoring of control could be effective.

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Disclosure

The author declares that she have no competing interests.

References

[1] Patra, N.C. and S. Mukhopadhayay, *Laboratory accreditation in India including latest ISO/IEC 17025: 2017: An overview.* Indian Journal of Pathology and Oncology, 2019. 6(1): p. 1-8.

[2] Tranchard, S. (2017). ISO/IEC 17025 - moves to final stage of revision, 2017. Available from: https://www.iso.org/news/ref2212.html, Accessed: 2017-06-06.

[3] Islek, D. S., & Yukseloglu, E. H. (2018). Accreditation of forensic science laboratories in Turkey in the scope of TS EN ISO/IEC 17025: 2017 standard. *Medicine Science*, *7*(4), 962-966.

[4] https://www.cofrac.fr - Importance of Accreditation for Supporting Social Action Health Systems, Accessed: 04-2018.

[5] Silva, V. V. M. dan Ribeiro, J. L. D. "Obtaining laboratory accreditation – required activities", International Journal of Health Care Quality Assurance.

[6] Kanitvittaya S, Suksai U, Suksripanich O (2016). Laboratory quality improvement in Thailand's northernmost provinces. International Journal of Health Care Quality Assurance.

[7] Kurniadi, D., & Amrina, E. (2020). Designing ISO/IEC 17025: 2017–Based Laboratory Quality Manual: A Case of Laboratory of Environmental Engineering in Andalas University. *International Journal of Progressive Sciences and Technologies*, *19*(1), 14-21.

[8] ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

[9] S. Tranchard, New edition of ISO/IEC 17025 just published, (Accessed on 1/12/17) https://www.iso.org/news/ref2250.html.

[10] U. Ricci, Establishment of an ISO 17025:2005 accredited forensic genetics laboratory in Italy, *Accred. Qual. Assur. 19* (2014) 289-299.

[11] Djamel Ghernaout, Mohamed Aichouni, Abdulaziz Alghamdi. Overlapping ISO/IEC 17025:2017 into Big Data: A Review and

Perspectives. *International Journal of Science and Qualitative Analysis*. Vol. 4, No. 3, 2018, pp. 83-92.

[12] S. Wong, Risk-based thinking for chemical testing, Accred. Qual. Assur. 22 (2017) 103-108.

[13] ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. *International Organization for Standardization/International Electrotechnical Committee, Geneva, 2017.

[14] ISO, ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories, (1/12/17) https://www.iso.org/publication/PUB100424.html (Accessed on 21/04/18).

[15] ISO, Discover the new ISO/IEC 17025:2017, (1/12/17) https://www.youtube.com/watch?time_continue=46&v=dH1K (Accessed on 21/04/18).

[16] C. N. Murphy, J. Yates, The International Organization for Standardization (ISO) (2009). Global governance through voluntary consensus, T. G. Weiss, R. Wilkinson (Eds.), Routledge Global Institutions, Taylor & Francis, New York.

[17] Vasilnakova, A. (2018). RISK MANAGEMENT IN ACCREDITED TESTING LABORATORIES. *Annals of DAAAM & Proceedings, 29*.

[18] Çuhadar, S. (2013). Preanalytical variables and factors that interfere with the biochemical parameters: a review. The Journal of Physiology and Biochemistry 2013, Vol. 2, No. 2, 2013, pp. 1-7.

[19] Neogi, S. S.; Mehndiratta, M.; Gupta, S. & Puri, D. (2016). Pre-analytical phase in clinical chemistry laboratory. Clin Sci Res, 2016, pp. 171-178.

[20] Lemos, D. T. & Almeida, D. L. T. (2001). Whole Life Cycle Risk Management. Assessment and Management of Environmental Risks 2001, 4, pp. 401-407.

[21] International Organization for Standardization. Medical devices - Application of risk management to medical devices ISO 14971: 2007. Geneva: International Organization for Standardization, 2007.

[22] Nichols, H. J. (2011). Laboratory Quality Control Based on Risk Management. Annals of Saudi Medicine 2011, Vol. 31, No. 3, pp. 223-228.

[23] Raz, T. & Michael, E. (2001). Use and benefits of tools for project risk management. International Journal of Project Management 2001, Vol. 19, No. 1, pp. 9-17.

[24] Boehm, W. B. (1991). Software Risk Management: Principles nad Practices. IEEE Software 1991, Vol.8, No.1, pp. 34-35.

[25] Kremljak, Z. (2010). Risk Management, Proceedings of the 21st International DAAAM Symposium, Vienna, ISSN 1726-9679, ISBN 978-3-901509-73-5, Katalinic, B. (Ed.), 127, Published by DAAAM International, Vienna,Austria, http://www.daaam.info/Downloads/Pdfs/proceedings/proceedings_2010/19106_Symp_1_head.pdf.

[26] Chapman, C. & Ward, S. (1997). Project Risk Management - Processes, Techniques and Insights; John Wiley & Sons Ltd: England, 1997, pp. 9-12.

[27] Hallikas, J.; Karvonen, I.; Pulkkinen, U.; Virolainen, V.-M. & Tuominen, M. (2004). Risk management processes in supplier networks. Int. J. Production Economics 90, 2004, pp. 47-58.

[28] Simsekler MCE, Kaya GK, Ward JR, Clarkson PJ. Evaluating inputs of failure modes and effects analysis in identifying patient safety risks. *Int J Health Care Qual Assur*. 2019; 32(1): 191-207.

[29] Rin, D. G. (2009). Pre-analytical workstations: A tool for reducing laboratory errors. Clinica Chimica Acta 2009, Vol. 404, No. 1, pp. 68-74.

[30] Rastogi, N. I. T. A. N. K., & Trivedi, M. K. (2016). PESTLE technique–a tool to identify external risks in construction projects. *International Research Journal of Engineering and Technology (IRJET)*, *3*(1), 384-388.

[31] Ogaro, H.M.; Kiiyukia, C.; Mbatha, S.; Ngayo, M.O. Biorisk Status: A Comparative Assessment of Private and Public Medical Diagnostic Laboratories in Western Kenya. Appl. Biosaf. 2018, 23, 47-54.

[32] Juma, B.W.;Wadegu,M.;Makio, A.; Kirera, R.; Eyase, F.; Awinda, G.; Kamanza, J.; Schnabel, D.;Wurapa, E.K. A Survey of Biosafety and Biosecurity Practices in the United States Army Medical Research Unit-Kenya (USAMRU-K). Appl. Biosaf. 2014, 19, 28-34.

[33] Samuel, S.; Kayode, O.; Musa, O.; Nwigwe, G.; Aboderin, A.; Salami, T.A.; Taiwo, S. Nosocomial Infections and the Challenges of Control in Developing Countries. Afr. J. Clin. Exp. Microbiol. 2010, 11, 102-110.

[34] AlShammari, W., Alhussain, H., & Rizk, N. M. (2021). Risk Management Assessments and Recommendations Among Students, Staffs, and Health Care Workers in Educational Biomedical Laboratories. *Risk Management and Healthcare Policy*, *14*, 185.

[35] Moazzam, M., Akhtar, P., Garnevska, E., & Marr, N. E. (2018). Measuring agri-food supply chain performance and risk through a new analytical framework: a case study of New Zealand dairy. *Production Planning & Control*, *29*(15), 1258-1274.

[36] Leat, P., & Revoredo-Giha, C. (2013). Risk and resilience in agri-food supply chains: The case of the ASDA PorkLink supply chain in Scotland. *Supply chain management: An international journal*.