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RISK BASED APPROACH: ISO/IEC 17025:2017 PERSPECTIVE

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Introduction

Let me start of by quoting the greatest, **Muhammad Ali** "*He who is not courageous enough to take risks will accomplish nothing in life*", close quote.

The risk based approach and the awareness of risks is accentuated in the new version of ISO/IEC 17025 standard and a risk-based thinking approach and process design in the laboratory is therefore promoted.

According to the standard ISO 31000, risk is the effect of uncertainty on the object. An effect, on the other hand, is a positive or negative deviation from what is expected.

Dealing with risks and opportunities in the laboratory is not a novelty. The previous version of ISO/IEC 17025 indirectly used the term risk almost in each chapter, particularly in the context of corrective and preventive actions but also associated with method validation, uncertainty of measurement and proficiency testing or inter-laboratory comparisons.

However, the term risk appear directly at least four times in the previous version compared to over thirty time in the latest version, subsequently confirming the need for risk based "thinking".

Even though the new version does not state a requirement for a formal risk assessment methodology, section 8.5.2 in the new standard expect laboratories to (a) plan actions to address risk and opportunities (b) implement the actions into the management system and (c) evaluate the effectiveness of these actions

How to assess risk in the laboratory

The framework, as illustrated in figure 1, is a typical example of a step-by-step risk assessment methodology that can be followed to ensure

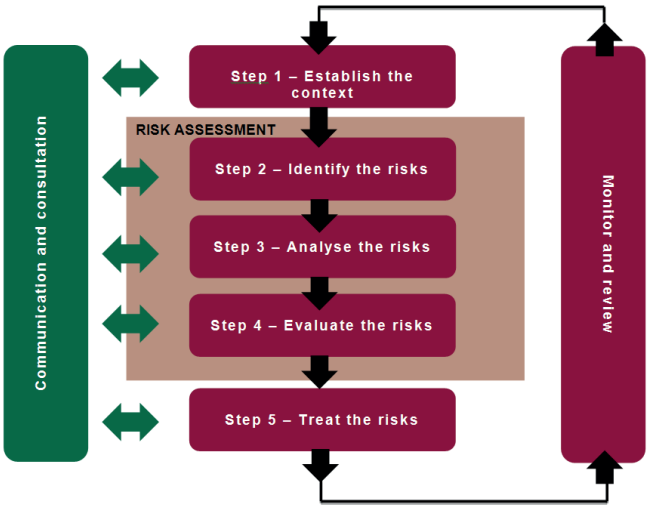

Figure 1: Step by step risk assessment methodology framework

effective implementation of the requirement of ISO/IEC 17025:2017, section 8.5.2. However, it is important to note that there are many other methodologies that can be followed to achieve the same objective.

The following provide a brief overview of the steps as illustrated in figure 1:

STEP 1: The first step is to identify the context

It is important to identify risks form the internal and external context of the laboratory. Although there is no requirement from which context may be identified from, the following types or categories provided guidelines form were context may be derived:

PROCESS RELATED RISKS: Risks of nonconforming output, process breakdown, process inefficiency etc.

QUALITY RELATED RISKS: Risk of defects and non-attainment of specified requirements

SUPPLIERS RELATED RISKS: Risk of defects and non-attainment of specified requirements

BUSINESS RELATED RISKS: Risks to business continuity, etc.

STEP 2: The second step is to identify the risks

Risk identification methods range from common sense, brainstorming, to the use of standards good practices such as the SWOT analysis.

The SWOT analysis is a process that identifies an organization's strengths, weaknesses, opportunities and threats. It can be used for brainstorming and identification of weaknesses and threats.

Table 1: SWOT Analysis

List of **S**trengths (internal positive factors)	List of **W**eaknesses (internal negative factors)
List of **O**pportunities (external positive factors)	List of **T**hreats (external negative factors)

STEP 3 and STEP 4: Analyze and evaluate the risk

Risk Evaluation is the process used to compare the estimated risk against the given risk criteria so as to determine the significance of the risk. **Risk evaluation** may be used to assist in the decision to risk treatment.

During this process, the influences and causes are analysed based on the risk scenario. Furthermore, a classification and evaluation of risks must be carried out. This assessment can either lead to the initiation of measures or the acceptance of the risk as such. If measures are taken, their effectiveness shall also be examined. It is possible that a risk may be accepted, ignored or minimised to reduce further impact.

A risk analysis and assessment can be conducted, for example, by a three-stage quotation system as illustrated in figure 2:

Risk Impact Analysis

One can use the two measures (1) probability of occurrence and (2) Impact of risk and plot on the risk Impact/probability chart to provide a quick and clear view of the priority one needs to give to each risks and allocate the necessary resources required.

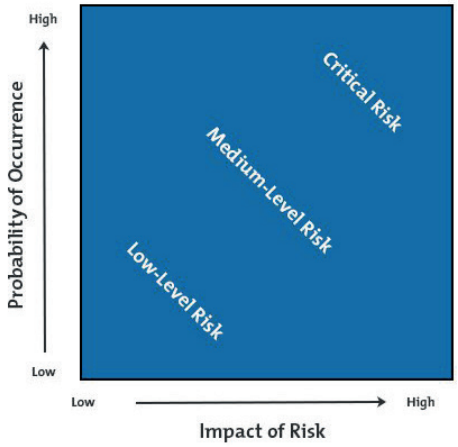

Figure 2: Example of a Risk Impact/probability chart

The corners of the chart above have the following characteristics:

Table 2: Characteristics of the Risk Impact/probability chart

Low impact/Low probability	The risks in the left corner are low level, and one can often ignore the risk
Low impact/High probability	Risk in the top left corner are of moderate level. In this case one can decide to cope with them and try to reduce their likelihood of happening
High impact/Low probability	Risks at the bottom right corner are of high importance if they do occur. However, they are very unlikely to happen. Therefore, one should do what he can to reduce the impact should they occur and have contingency plans in plan in case they happen
High impact/High probability	Risk towards the top right corner are very critical and one should pay attention to those risks

STEP 5: Risk mitigation or treatment

Risk mitigation is defined as taking steps to reduce adverse effects. There are four types of risk mitigation strategies that hold unique to disaster recovery. It is important to develop a strategy that closely relates to and appropriate to the risk and matches your company's profile. These four steps are explained in the following section:

Risk Acceptance: Risk acceptance does not reduce any effects however it is still considered a strategy. This strategy is a common option when the cost of other risk management options such as avoidance or limitation may outweigh the cost of the risk itself. A laboratory that doesn't want to spend a lot of money on avoiding risks that do not have a high possibility of occurring will use the risk acceptance strategy.

Risk Avoidance: Risk avoidance is the opposite of risk acceptance. It is the action that avoids any exposure to the risk whatsoever. Risk avoidance is usually the most expensive of all risk mitigation options.

Risk Limitation: Risk limitation is the most common risk management strategy used by businesses. This strategy limits a company's exposure by taking some action. It is a strategy employing a bit of risk acceptance along with a bit of risk avoidance or an average of both. An example of risk limitation would be a company accepting that a disk drive may fail at some point and avoiding a long period of failure by having regular backups.

Risk Transference: Risk transference is the involvement of handing risk off to a willing third party. For example, numerous companies outsource certain operations such as customer service, payroll services, etc. This can be beneficial for a company if a transferred risk is not a core competency of that company. It can also be used so a company can focus more on their core competencies.

The steps to consider during the risk assessment methodology is to ensure that (1) there is constant communication to the affected parties and (2) the process is monitored and reviewed for effectiveness.

Conclusion

Assessing and auditing the risk requirement will be challenging task yet interesting for both assessors and accredited laboratories.

Laboratories need to embrace the responsibility and decide which risks and opportunities to be addressed.

The accreditation body, on the other hand, has the responsibility to assess whether the laboratory have identified and taken appropriate actions for dealing with risk and opportunities.

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