AN INTRODUCTION TO RISK CONSIDERATION

Introduction

The aim of this cookbook is to provide basic concepts and simple tools and possibilities of applying the "considering of risks and opportunities" in the framework of the ISO/IEC 17025:2017.

The risk based approach and the awareness of risks is emphasized in the new version of the standard and a risk-based thinking approach and process design in the laboratory is promoted, although ISO 9001:2015 and ISO/IEC 17025:2017 do not stipulate a complete risk management system (RMS) that meets, for example, the requirements of ISO 31000.

Dealing with risks and opportunities in the laboratory is not a novelty. The previous version of ISO/IEC 17025 already used the term risk in several chapters, particularly in the context of corrective and preventive actions, but also in connection with the validation of methods and the introduction of the concept of uncertainty of measurement. If a laboratory knows its risks, it has the capability to assess/prioritize them and is also aware of its consequences. It will be easier to plan how to handle risks and their effects. Mistakes or nonconformities detected at an earlier stage allow the laboratory to react early. Financial penalties or other heavy losses might be averted. The main objective is not to minimize risks, but in fact to optimize the risk and opportunity profile defined in the laboratory’s strategy.

The requirements of ISO/IEC 17025:2017

The international standard ISO/IEC 17025:2017 states in its introduction:
This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

The laboratory is responsible for deciding which risks and opportunities need to be addressed. However, the accreditation body assesses whether the laboratory has established appropriate actions for dealing with risks and opportunities.

The standard explicitly refers to the concept of risk in the following chapters:

- Foreword,
- Introduction,
- Clause 4.1.4 and 4.1.5 on impartiality,
- Clause 7.8.6.1 considering risks associated with the decision rules used in reports,
- Clause 7.10.1 related to nonconforming work,
- Clause 8.5 on actions to be implemented to address risks and opportunities,
- Clause 8.6 on improvement,
- Clause 8.7 on corrective actions,
- Clause 8.9 on management reviews.

Clause 8.5 “Actions to address risks and opportunities” sets minimum requirements for laboratories which shall be considered. The exploitation of improvement potentials according to improvement should always be aligned with the aim and purpose of laboratory activities.

Mind the NOTE to Clause 8.5.2:

"Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards."

Conversely, a minimum of formalism allows the laboratory to capitalize on the approach and motivate more effectively the deployment of provisions, sometimes perceived as constraints only.

Some words may encourage the consideration of related risks, thus supporting the implementation of requirements.

Examples:

- sufficient (clauses 7.2.1.2, 7.5.1),
- suitable (clauses 6.3.1, 8.3.2),
- prevent (clauses 5.6.c, 6.3.4, 6.4.3, 6.4.9, 6.4.12, 7.7.3, 8.3.2, 8.5.1.c),
- ensure (clauses 5.5.c,)
- critical (clauses 7.6.3, 7.8.2.1).

Terms and definitions related to risks
Various definitions of the term "risk" can be found in normative documents. The following definitions are freely derived from them.

Risk: what makes achieving an objective uncertain.

Level of Risk: an expression of the importance of the risk, taking into account the consequences and the likelihood of situations

Risk evaluation: comparison of the level of risk with an acceptance criterion

Addressing risks:
Many options are possible and can be combined: avoiding the risk, taking the risk to seize an opportunity, eliminating the source of the risk, changing the likelihood of occurrence or consequences, risk sharing or accepting the risk, and informing about it.

Residual risk: Risk remaining after addressing the risk

Opportunity: an event with potential positive consequences for the organization

How to assess risks in a laboratory?
To identify risks, it is useful to consider both the internal and external context of the organization (risks related to the customer, the supplier, but also the customer of the client and other stakeholders).

Risk identification methods range from common sense and brainstorming, via the use of pre-established lists for each subject area, to the use of standards setting good practices.

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

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)

The 4 boxes are filled with the relevant information ranked by decreasing importance.

For example:
Guidelines on risk management give various approaches.

The assessment of risks can be addressed answering the following questions:

- What can happen and why (risk identification)?
- What are the consequences?
- How likely is a future occurrence?
- Are there any factors that mitigate the consequences of the risk or reduce the probability of the risk?

To address risks in the laboratory adequately a thorough analysis of the risks to which a laboratory is exposed it should be started. The objective should be to indicate certain weaknesses in the laboratory activities.

The influences and causes are analyzed based on the risk scenario. Furthermore, a classification and evaluation of risks shall be made. This assessment can either lead to the initiation of measures or acceptance of the risk as such. If measures are taken, their effectiveness shall also be examined. It is possible that a risk is acceptable.

The risk scenario is often easy to define. Here, similar considerations can be made as in the case of "preventive measures". However, the classification and evaluation of risks is more difficult. To be able to carry out an assessment, the impact, the probability of occurrence and the probability of a risk being discovered quickly should be assessed.

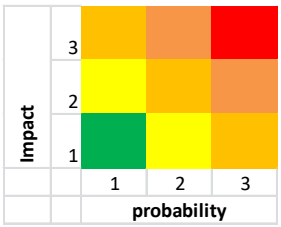
It is helpful to share a scale of value within the organization, regardless of the representation: quantitative or qualitative, represented in tables, in graphs etc.

For example, a risk assessment can be conducted for example by a three-stage quotation system:

Impact:

- low (1) - easily to correct - low impact
- moderate (2) - errors occurring but already clear (e.g. credibility loss)
- high (3) - serious errors with possibly irreparable consequences (up to danger to life and health)

Probability of entry: very rare (1), rare (2) or frequently (3)
The three-stage system results in a five-step risk assessment.



The lowest risk (1/1 - green) can be classified as an acceptable risk, whereas the highest risk (3/3 - red) usually requires immediate measures.

In the case of a small risk (yellow), it is necessary to decide whether it is still acceptable or whether measures need to be taken.

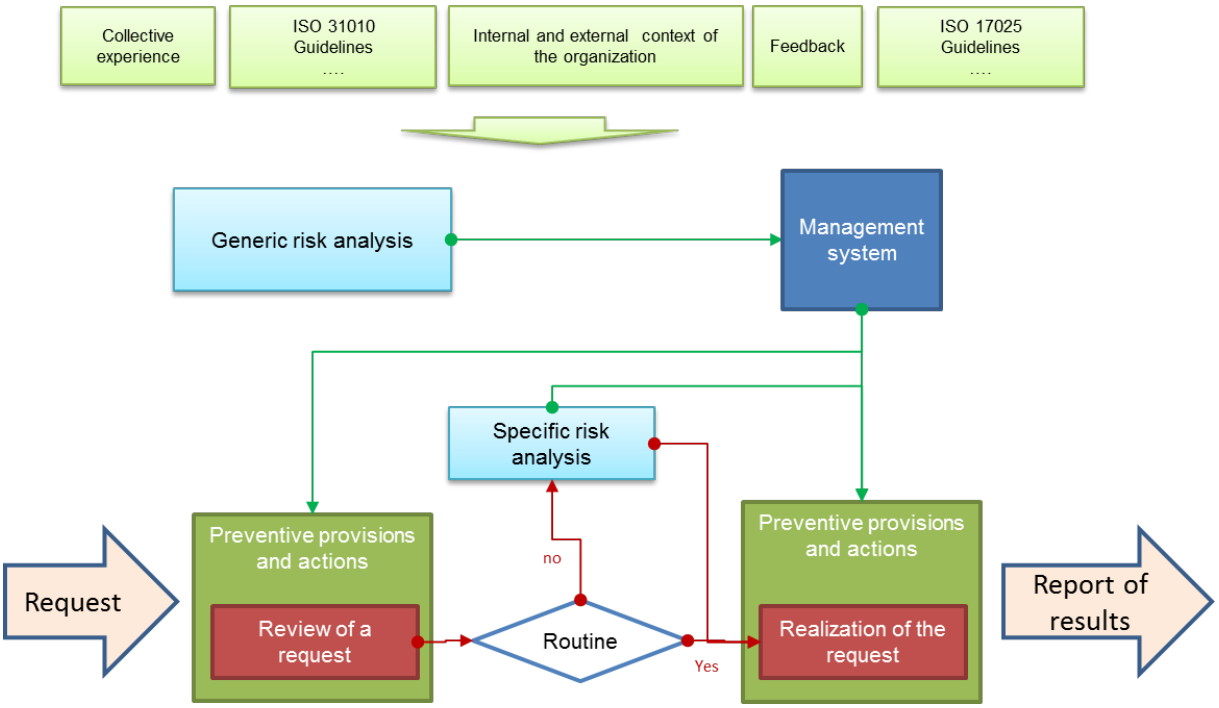
When are risk assessments carried out?
Answer: Whenever necessary (e.g. by customer requirements or by requirements of ISO/IEC 17025) or if it helps to achieve the objectives of the management system. This may be regular or occasional in case of abnormalities or changes in the laboratory procedures.

In fact, the laboratory should face risks (e.g. its existence, its impartiality, the validity of its results, etc.) that may lead to failures, losses, damages or others and may counteract them appropriately either by establishing a RMS or by other measures.

Clause 4.1.4 of ISO/IEC 17025 requires identifying risks on an on-going basis. For example, for some personnel on-going handling of risks can be ensured through a self-declaration of conflict of interest. This is reviewed once a year and needs to be updated when a new situation affecting impartiality arises.

Application in a more general context
The organization can follow a more or less explicit risk policy as needed. This can include the management of activities, financial management, safety, etc. The mechanisms for updating information can be more or less elaborated, ranging from risk management to mere reaction to failures.

The following example shows a mechanism for setting up preventive measures based on risk analyzes. Many other approaches are possible.



For further information:
ISO 31000:2018 Risk management – Guidelines
ISO/IEC 31010:2009 Risk management – Risk assessment techniques