

## Risk and Opportunities in Test Laboratories (Part I)

The Introduction clause of the newly revised ISO/IEC 17025:2017 categorially states that *“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.”*

This risk-based thinking is a totally new concept for accredited laboratory operators, although those familiar with ISO 9001 certification are aware of the importance of systematic approach in risk assessment and evaluation in order to avoid or mitigate any negative impact to the business.

From the perspective of laboratory process, one can easily realize there are potential risks in its routine operation. Apart from the commonly discussed business financial risk and occupational safety and health risks, the new ISO standard has suggested to put some risk consideration on

- impartiality,
- confidentiality,
- deviation/non-conformity during technical execution, and
- in issuing statement of conformance testing followed by making a decision rule or rules.

Those laboratory management which has already been undertaking regular management reviews that look at improvement opportunities are likely to find that they might already meet the first three of the above requirements.

Qualitative risk assessment may be made for impartiality, independence and technical deviation and/or non-conformity. Quantitative risk assessment, however, and decision rules are to be applied in issuing statement of conformance to a specification or a regulatory limit because measurement uncertainty of the test result plays an important part in making such a decision on conformity.

## What is “risk”?

In ISO 9000:2015, “*Quality management systems—Fundamentals and vocabulary*”, risk is defined as the “**effect of uncertainty on an expected result.**” Its notes in the definition further describe risk as a “*deviation from the expected,*” either positive or negative. It is recognized that **risk** is inherent in all aspects of a quality management system.

Therefore, to an accredited laboratory, risk is the chance, likelihood or probability, high or low, of incorrect or “invalid” measurement-based decisions in the laboratory analysis. We need to cultivate such risk-based thinking in our daily operation, as it can be helpful to identify opportunities. In other words, we have to map and manage our laboratory’s risks and develop ability to minimize risks in our laboratory operation. This can lead us to increase clients’ confidence in our test data and provide opportunities for further advancement of business.

## Practical steps for risk-based thinking

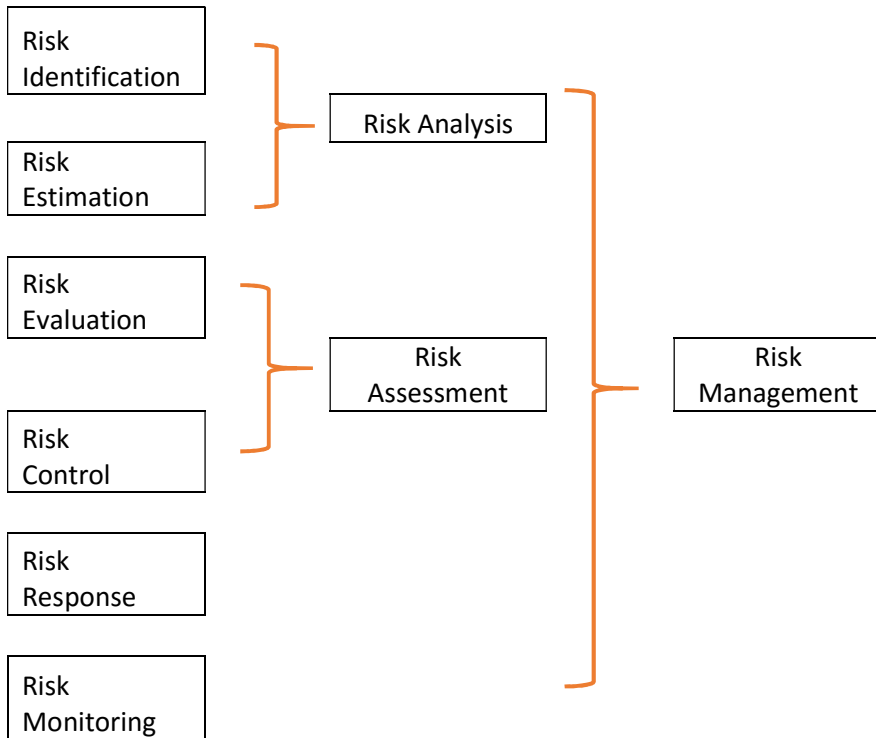
- 1) **Risk identification** : Systematic use of information to identify harm or hazards;
- 2) **Risk estimation** : Use assigned or rating values to the probability of occurrence of harm and its severity (e.g. using 1 for not expected to occur and unlikely to cause an impact, respectively, and 5, almost certain to occur and catastrophic, respectively);
- 3) **Risk evaluation** : Compare the estimated risk against some risk criteria by organization concerned, to determine the acceptability of the risk;
- 4) **Risk control** : Process used to make decision and implement measures so that the risks are reduced or, at maintained within specified level;
- 5) **Risk response** : When a risk triggers, whether anticipated or not, respond promptly. If there is a contingency plan for the problem, begin its execution as soon as practical;
- 6) **Risk monitoring** : Be part of risk response planning to monitor for specific risk triggers; also status collection and regular variance analysis provide general risk monitoring.

It may be noted that:

**Risk analysis** covers both risk identification and risk estimation, whilst **risk assessment** includes the risk analysis and risk evaluation. Finally, we have to conduct **risk management** which covers the risk assessment, risk control, risk response and risk monitoring.

Schematically, their relationship can be seen in Figure 1.

**Figure 1: Relationship of various risk management components**



*(to be continued....)*