Risk and Opportunities in Test Laboratories – Part II

Practical approaches in risk management

The very first step in risk-based thinking is to identify and prepare a list of possible risks in running the laboratory operation. Such Risk Register is important and shall be documented. After the **risk identification** process, we have to decide whether to deal proactively with a significant risk which has the likelihood that it will occur (typically, these will have at least moderate probability and impact).

All assessment of risk depends on determining risk probability it will occur and risk severity on its impact if it occurs. Mathematically, it is calculated as:

Risk Index (RI) estimation = Frequency (F) x Severity (S)

where F can be scaled for example, from 1 to 5, and S, from 1 to 5, too.

a) Qualitative risk analysis

Qualitative analysis combines range estimates of these two factors to prioritize the risk under study. Instead of working on the ordinal ranking units of 1 to 5 where unit 5 is designated as high risk, we may use category ranking by defining probability ranges between these limit, using defined percentages, such as:

- High : 50 percent or higher probability
- Medium : Between 10 and 50 percentage probability
- Low : Less than 10 percentage probability

Severity of impact can be difficult to define as it has many dimensions. Impact may be measured in many different ways, such as time, cost, effort, scope change, customer trust, team confidence, etc. You may have to consider the opinions of as many people as possible to build up more confidence in this estimate.

For qualitative risk assessment, severity of impact can also be given category ranking of High, Medium and Low.

Seek the root cause of each risk to manage. We may use cause-and-effect analysis to determine the source(s) of the risks, striving to better understand the risks and to determine whether they are controllable or uncontrollable. Probe deeply to uncover the source of each risk, not just its symptoms.

Example 1:

Laboratory A is unable to perform Dioxin analysis using HRGCMS technique as it does not have the appropriate instrument. The analysis is part of a large contract which involves analysis of other test parameters on some 200 soil and groundwater samples. It wishes to sub-contract the analytical work to Laboratory B which has the right

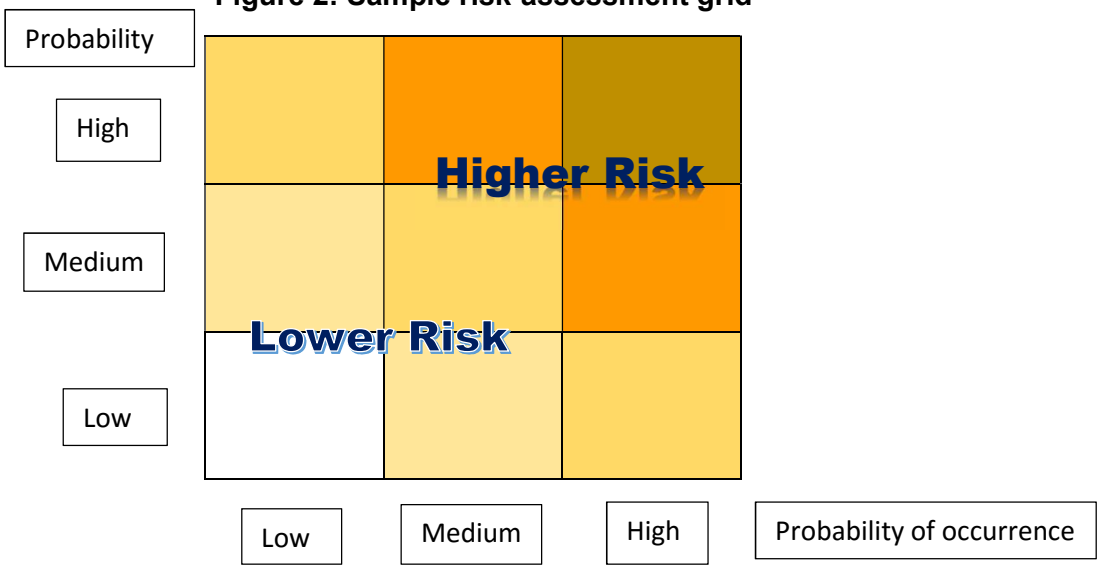
equipment but has not been accredited yet. A technical audit upon visiting the Laboratory B revealed that the staff handling the analysis was not so well verse technically. Closer supervision might be required. Is there a risk to sub-contract the Dioxin analysis to Laboratory B?

Qualitative risk analysis suggested that:

a. The frequency of requiring such Dioxin analysis is high due to large number of samples in hand
b. Although the Laboratory B management promised to provide more training to the technical staff concerned whilst undertaking the sub-contracting works, Laboratory A Technical Manager was of the opinion that there could be a medium risk involved of getting reliable data from the sub-contractor.
c. Considering the large number of samples for Dioxin analysis with a medium risk of adverse impact, the Laboratory A management decided that Laboratory B is not so acceptable and would look for another Dioxin laboratory which has an approved accreditation.

For a simple qualitative assessment, we can use a risk-assessment matrix to place risks in two-dimensional grid. Categories of probability and impact severity define where in the matrix each potential exposure falls, with the most severe toward the top and the right. Figure 2 shows a sample risk-assessment matrix.

Figure 2: Sample risk-assessment grid



b) Quantitative risk analysis

Generally, qualitative risk analysis is done for all listed risks to determine which risks may justify more precise quantitative analysis. In fact, quantitative analysis requires

greater effort, but it generates absolute estimates of risk probability and impact for the most severe risks.

For quantitative risk analysis for likelihood of occurrence, we use a specific numerical percentage between zero and 100, in the place of the ranges used for qualitative analysis. There are three ways to estimate probabilities:

a) Calculate a prediction based on a mathematical model
b) Perform an empirical calculation using historic data
c) Select a number based on the best analysis available (*guessing!*)

We can use assigned or rating units of 1 to 5 to describe the probability of occurrence found in percentage, as rare, remote, occasional, frequent and almost certain, respectively.

The categories of impact severity used in qualitative analysis also must be precise, requiring defined units and a numeric estimate of measurement.

For some risks, a single estimate will be appropriate, but for others it may be best expressed as a statistical distribution or a histogram. Quantitative risk impact is measured in days, money, effort, or some other suitable unit. There can be more than one of these units in most risks assessed.

Again, we can assign rating units of 1 to 5 to represent the severity of risk impact, being negligible, minor, moderate, major and catastrophic, respectively.

In summary, we have the following factors of the probability of occurrence and severity of impact in Table 1 below:

Table 1: Factors for risk estimation

Frequency of Occurrence	Rating	Description
Rare	1	Not expected to occur
Remote	2	Not likely to occur
Occasional	3	Possible or know to occur
Frequent	4	Common occurrence
Almost certain	5	Continual of repeated occurrence

Severity	Rating	Description
Negligible	1	Not likely to cause any impact
Minor	2	No significant impact
Moderate	3	Having very slight impact
Major	4	Having considerable impact
Catastrophic	5	Having significant impact

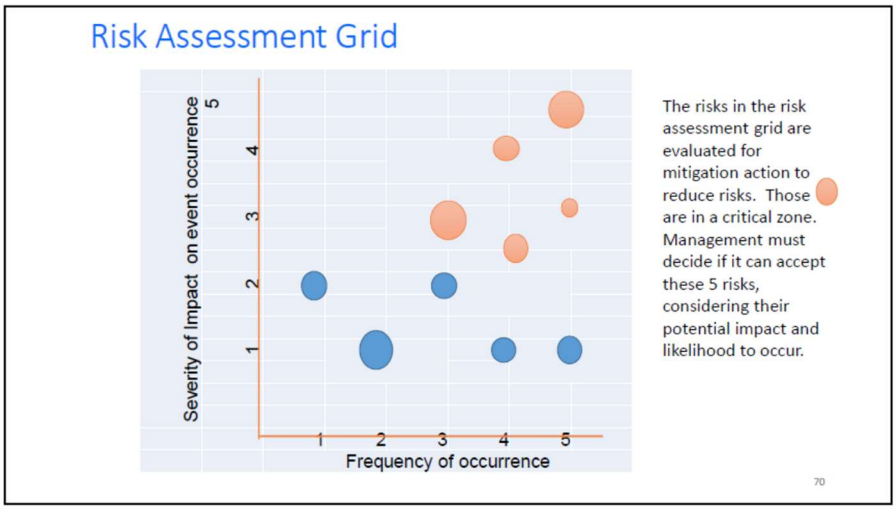
We can carry out **risk estimation** or measure in terms of Risk Index (RI) by using a 5x5 matrix as shown below:

Table 2: A 5 x 5 matrix for risk estimation

RISK INDEX

Severity \ Frequency	Rare (1)	Remote (2)	Occasional (3)	Frequent (4)	Almost Certain (5)
Negligible (1)	1	2	3	4	5
Minor (2)	2	4	6	8	10
Moderate (3)	3	6	9	12	15
Major (4)	4	8	12	16	20
Catastrophic (5)	5	10	15	20	25

Such risk estimation may also be visualized by plotting a risk assessment grid, as shown in Figure 3 below.



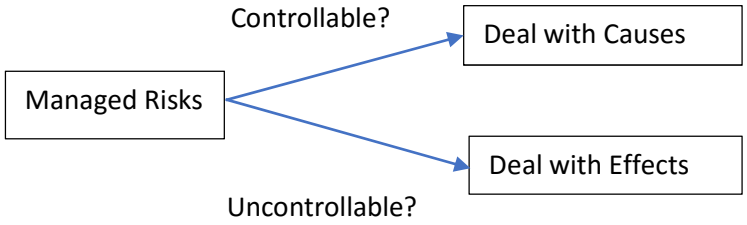
c) Risk evaluation

To carry out a **risk evaluation**, the laboratory management has to set some risk criteria to determine the acceptability of such a risk. In fact, such risk criteria must be prepared when the risks are being identified to be probably significant. It is utmost important that knowing what the risks are is one thing but knowing what to do about them is another.

Therefore, when identifying risks, identify a response as well so you know how you are going to act if and when a risk actually happens or so you can put controls and checks in place to prevent a risk from occurring in the first place.

The risk response strategies can be summarized in Figure 4:

Figure 4: Risk response strategies



When risk sources are under control, *preventive strategies* may provide solutions; for uncontrollable risks, risk management requires *recovery strategies* to deal with the adverse effects.

d) Risk response

There are four ways of **risk responses** in a risk-management strategy:

- **Avoid** – change it to eliminate the threat. For example, if you find the laboratory analyst is not well verse in using an analytical instrument software, in order to avoid this risk, it is better to replace the staff by a more experienced one whilst provide more training to the staff concerned.
- **Transfer** – shift the risk to another party. For example, by sub-contracting an unfamiliar test to a third party so let them bear the risk.
- **Mitigate** – reduce the probability or impact of the risk. You do not have the experience in a LIMS software. So, you engage the software supplier to conduct a 2-week intensive training for your staff.
- **Accept** – choose to accept the risk and develop a contingency plan. For example, you have just found out that your certified reference material in hand has just passed its expiry date but the new order has yet to be received. You need to use the CRM today urgently. So, you decide to take a risk to use it whilst sending a sub-sample to your competition to verify the results as a contingency plan.

e) Risk management, monitoring and control

Risk management is implemented to minimize the negative effects that uncertain occurrences can have in your laboratory operation. You have to develop and refine your risk management plan which lays out strategies to manage and to control these uncertain events. The plan must be regularly updated regularly. The risk management plan includes but not limited to:

i. Risk factors
ii. Associated risks
iii. Your assessment of the likelihood of occurrence and the consequences of each risk
iv. Your plan for managing selected risks
v. Your plan for keeping people informed about these risks regularly

Identifying who is responsible for each deliverable

To keep track with who is responsible for each deliverable in risk control and management, the key personnel must be registered in a Risk Register document, listing their responsibilities in managing the risks involved. The degrees of responsibility for each person can be as below:

Responsible (R) - those who have to do the work in the task

Accountable (A) - the person who has to ultimately answer for the task getting completed; only one person can be accountable for each task

Consulted (C) - Those whose opinions and information you seek

Informed (I) - Those who are kept informed on the project

Document risks and specific consequences

For significant-activity-related risks assessed quantitatively, document measured risk consequences in the Risk Register. Select significant risks for risk response planning. We can go one step forward to aggregate the quantitative risk assessment information to assess the overall laboratory operation risk as well.

Communicating about risks

We tend to not often share information about laboratory risks or not at all. As a result, the laboratory operation may suffer unnecessary problems and setbacks that proper communication may have avoided.

Hence, we should communicate about risks early and often. Such information can share with the key team members and newly recruited staff. Encourage the staff to discuss potential risks and their likelihood of occurrence, and address problems as soon as those problems occur. This can be carried out at regularly scheduled staff meetings and at annual upper-management review meeting, with progress reports.

Risk-related communication can be improved with the staff by:

i. Explaining in detail what the risk is, how it may affect the work, and how you estimated the likelihood of its occurrence
ii. Telling people what the current chances are that certain risks will occur, how you are minimizing the chances of problems, and how they can reduce the chances of negative consequences
iii. Encouraging people to think and talk about risks, always with an eye toward minimizing the negative impact of these risks
iv. Documenting in writing all the information about the risks.