

*If risk assessments are a necessary part of your role, but keeping on top of them and managing the process can take up too much of your valuable time, this White Paper will help. **Craig Bunn, Vice President of Product Strategy and Quality** at Genial explains how to simplify risk assessments, save time and also evaluate risk using a risk matrix.*

Ensuring risk assessments are completed correctly for many different risks can be problematic, keeping track of these multiple risk assessments across multiple departments can be even harder, ensuring that they are reviewed as required and reporting on these can take considerable effort.

To complete a risk assessment and keep this up to date should not require a full-time risk and Excel™ expert, given the correct tools experts in their field should be able to identify and mitigate risks.

## **Key Benefits**

- Simplify risk assessments  
Building templates for each type of risk assessment gives you the flexibility and control to manage any risk
- Enhanced visibility  
Easily see from one system all risks and risk assessments, high risks, non-mitigate risks, outstanding actions
- Multi-disciplinary approach  
Allow input, review and comment from different departments when working on larger projects

## **Risk Based Thinking**

According to ISO (2018a) managing risks consists of systemically applying policies, procedures and practices to the risk analysis and evaluation, as well as monitoring and controlling tasks. Or, perhaps put more simply, a risk is an unexpected event that may or may not occur, and these risks can be associated to any aspect or stage of the project you are looking at.

Risk methodologies and associated methods have been in common use across many industries, such as automotives, aerospace, healthcare, for several years now; with these risk methodologies incorporating many different risk approaches (Marhaviilas et al. 2011).

ISO 9001:2015 introduced a Risk-Based Thinking (RBT) model, the purpose of this was to introduce a risk approach that could be implemented across the entire organisation and thus encouraging organisations to undertake long-term thinking and to put risk prevention at the forefront of their collective minds and not simply risk assessments (Martins, Silva, Gabriel, 2021). The standard also introduced the process-based approach, incorporating this process-based approach requires the involvement of the whole organisation across all QMS activities which includes RBT (Fonseca et al, 2019).

It is important to note that RBT requires organisations to evaluate risk, this is a little different from a risk assessment. However, one of the most effective ways to evaluate a risk is by performing a risk assessment.

It is also important to remember, risks are not always a negative thing, this can be seen why looking at opportunities and associated risks.

So what tools are available to perform a risk assessment as part of your RBT?

## **The Risk Matrix**

The risk matrix is one of the most widespread tools evaluating risk, with the primary purpose being to determine the size of the risk concerned and if the sufficient controls in place. This is what we shall focus on here.

A risk matrix is a matrix consisting of the combination between the scale of the probability of occurrence of the causes leading to the nonconformity and the scale of severity of effects, we'll be using this terminology throughout this document. These matrix axes have synonyms including likelihood & consequence, these can vary across industry sectors.

The matrix can be used for any risk from assessing the harm in a single harm-severity method for medical devices to organisational opportunity risk, and all risk in between.

At the start of any project, it is important to use a risk appetite or risk acceptance criteria when utilising a risk matrix approach.

What size grid to use?

The matrix is a two-dimensional grid looking at Probability and Severity, the combination of these provides a place on the risk matrix and thus a risk value.

The grid size can range from 3x3, 4x4, to 5x5; the smaller the matrix generally the simpler they are to use but they do not provide the granularity of the larger matrix size, as such it is generally used to provide a somewhat informed decision about a risk quickly.

The 5x5 matrix allows for the greatest granularity and provides the most clarity in the results; for some projects this might be too much granularity, as the larger the matrix the more work is involved.

What might you normally use to identify the axis on a 5x5 matrix?

This does vary across industry sectors, but a typical set of entries would be:

### Probability

1. Improbable
2. Unlikely
3. Occasional
4. Likely
5. Frequent

### Severity

1. Negligible
2. Minor
3. Moderate

4. Significant
5. Catastrophic

There are many other options that could be used, iPassport allows you to adjust these to your own requirements as part of the template structure. These entries would normally be identified in your risk management policy or similar document, providing guidance on what each of the entries mean in context.

The values assigned would be those used to undertake the calculation, this would normally be a multiplication of the likelihood and severity e.g. an unlikely probability and a moderate severity would be  $2 \times 3 = 6$ .

But what does six represent in this instance?

This is just a number, but this number would be identified in the risk value, this shows what the values represent. Typically, in a 5x5 grid a risk value of 6 would be a medium risk.

A typical structure would be:

- 1 – 2 = Very Low
- 3 – 5 = Low
- 6 – 9 = Medium
- 10 – 14 = High
- 15+ = Very High

There are of course variances in this structure so it is important to allow for this, for example the risk value could stretch over the range e.g.  $6 - 10 = \text{Medium}$  and  $10 - 14 = \text{High}$ .

How do we know if we can accept the risk?

This shall be based on the risk appetite, risk acceptance criteria, or your risk threshold. This is normally described in your risk management policy and provides the acceptance criteria that allows you to accept the risk either with or without additional controls.

To ensure that one tool can be used across different departments any risk management tool should allow you to configure your own risk values, iPassport allows you to do this, so that you have different acceptance criteria for different projects or departments.

It is important to note that one size often does not fit all in risk assessment, so providing the tools to build a risk template for different scenarios is ideal.

How low should a risk be?

There is no right answer for this, the concept of As Low As Reasonably Practicable (ALARP) is the a great place to start and is something that you can find in a number of guises across health and safety regulations, sometimes referred to as SFAIRP with the two terms essentially meaning the same thing. The process involves weighing the risk being considered against the trouble, time and money needed to control it.

If you have reduced a risk ALARP does this mean you accept it?

No, you do not have to accept this risk and you might wish stop undertaking that process. The risk has been considered and you have thought about how to reduce this ALARP but it still might fall above your risk threshold, if this is the case then the risk can be rejected and you can stop that activity.

So how do we reduce a risk to an acceptable level?

The key message is to reduce risk by reviewing and adding controls, not by tweaking the numbers!

This might sound obvious, but many risk assessments have had the risk reduced simply by reviewing the numbers or adding a mitigation note without adding any further controls.

There are two types of uncertainty, aleatory uncertainty, and epistemic uncertainty, and it is important to acknowledge these two different types to have an effective management system. Aleatory uncertainty cannot be reduced whereas epistemic uncertainty can be reduced by looking for more knowledge which helps to predict the outcomes, that is thinking about more controls that can be put in place to reduce the risk.

A control should feed into your mitigations, any further controls should be actioned and added in when complete. See what your risk would be if all the possible controls were added, to do this think about current and future controls and undertake a residual risk assessment which would tell you the risk value if all controls were in place. If this is still too high see if there any further controls, if not then a decision needs to be made to override or simply stop the process.

iPassport provides the tools to complete this residual risk assessment, allowing you to easily see what your current risk is and what it could be reduced to. This benefits you when deciding the initial risk and in ALARP.

The difficulty comes in ensuring that everyone is aware of the risk threshold for the assessment, if this is not understood then it is not possible for the staff members to undertake a successful risk assessment.

Providing the tools to allow this to be established in a controlled template and providing those visual cues to staff means that the guess work is removed, and more trust can be placed in the risk assessment.

iPassport can provide you with these powerful tools to help you create your risk assessment templates, perform your risk assessments, stay informed about the progress of the risks and ensure that all staff can clearly see risk assessments when needed.

## **Summary**

You should not need to be an Excel™ genius to link multiple risk assessments together, fix the broken cells and calculations and you should not have to manually follow-up on these just to see the progress; you should also not have to create and manage multiple templates and ensure that they are being populated as required.

These are all things that iPassport risk can do for you, you build the template, which is then fully managed and auditable, you can control the fields, marked required elements, get automatic notifications, and ensure the correct calculations are in place. Not only that searching for risk assessments and individual risks is simple and can easily be reported on.

No more hunting for the risk assessment, seeing if it has been completed correctly and chasing people up to complete them.

Get time back while increasing the reliability of your risk assessments.

To learn more please contact our sales team [sales@genialcompliance.com](mailto:sales@genialcompliance.com) or visit our website [www.genialcompliance.com](http://www.genialcompliance.com)

## References

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