



**International Organization for Standardization**

BIBC II, Chemin de Blandonnet 8 , CP 401, 1214 Vernier, Geneva , Switzerland

Tel: +41 22 749 01 11, Web: [www.iso.org](http://www.iso.org)

## RISK-BASED THINKING IN ISO 9001:2015

### Purpose of this paper

- to explain risk-based thinking in ISO 9001
- to address perceptions and concerns that risk-based thinking *replaces* the process approach
- to address the concern that preventive action has been removed from ISO 9001
- to explain in simple terms each component of risk-based thinking

### What is risk-based thinking?

One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to considering risk, rather than treating “prevention” as a separate component of a quality management system.

Risk is inherent in all aspects of a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the quality management system.

In previous editions of ISO 9001, a clause on preventive action was separated from the whole. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Risk-based thinking is something we all do automatically in everyday life.

*Example: If I wish to cross a road I look for traffic before I begin. I will not step in front of a moving car.*

**Risk-based thinking has always been in ISO 9001 – this revision builds it into the whole management system.**

*In ISO 9001:2015 risk-based thinking needs to be considered from the beginning and throughout the system, making preventive action inherent to planning, operation, analysis and evaluation activities.*

**Risk-based thinking is already part of the process approach.**

Not all the processes of a quality management system represent the same level of risk in terms of the organization’s ability to meet its objectives. Some need more careful and formal planning and controls than others.

*Example: To cross the road I may go directly or I may use a nearby footbridge. Which process I choose will be determined by considering the risks.*

Risk is commonly understood to have only negative consequences; however the effects of risk can be either negative or positive.

In ISO 9001:2015 risks and opportunities are often cited together. Opportunity is not the positive side of risk. An opportunity is a set of circumstances which makes it possible to do something. Taking or not taking an opportunity then presents different levels of risk.

*Example:*

*Crossing the road directly gives me an opportunity to reach the other side quickly, but if I take that opportunity there is an increased risk of injury from moving cars.*

**Risk-based thinking considers both the current situation and the possibilities for change.**

*Analysis of this situation shows opportunities for improvement:*

- *a subway leading directly under the road*
- *pedestrian traffic lights, or*
- *diverting the road so that the area has no traffic*

## **Where is risk addressed in ISO 9001:2015?**

The concept of risk-based thinking is explained in the introduction of ISO 9001:2015 as an integral part of the process approach.

**ISO 9001:2015 uses risk-based thinking in the following way:**

**Introduction** - the concept of risk-based thinking is explained

**Clause 4** - organization is required to address the risks and opportunities associated with its QMS processes

**Clause 5** – top management is required to

- Promote awareness of risk-based thinking
- Determine and address risks and opportunities that can affect product /service conformity

**Clause 6** - organization is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them

**Clause 7** – organization is required to determine and provide necessary resources (risk is implicit whenever “suitable” or “appropriate” is mentioned)

**Clause 8** - organization is required to manage its operational processes (risk is implicit whenever “suitable” or “appropriate” is mentioned)

**Clause 9** - organization is required to monitor, measure, analyse and evaluate effectiveness of actions taken to address the risks and opportunities

**Clause 10** - organization is required to correct, prevent or reduce undesired effects and improve the QMS and update risks and opportunities

## Why use risk-based thinking?

By considering risk throughout the system and all processes the likelihood of achieving stated objectives is improved, output is more consistent and customers can be confident that they will receive the expected product or service.

Risk-based thinking:

- improves governance
- builds a strong knowledge base
- establishes a proactive culture of improvement
- assists with statutory and regulatory compliance
- assures consistency of quality of products and services
- improves customer confidence and satisfaction

Successful companies intuitively incorporate risk-based thinking.

## How do I do it?

Use risk-based thinking in building your management system and processes.

### Identify what your risks are – it depends on context

*Example:*

*If I cross a busy road with many fast-moving cars the risks are not the same as if the road is small with very few moving cars. It is also necessary to consider such things as weather, visibility, personal mobility and specific personal objectives.*

### Understand your risks

What is acceptable, what is unacceptable? What advantages or disadvantages are there to one process over another?

*Example:*

*Objective: I need to safely cross a road to reach a meeting at a given time.*

- *It is UNACCEPTABLE to be injured.*
- *It is UNACCEPTABLE to be late.*

*Reaching my goal more quickly must be balanced against the likelihood of injury. It is more important that I reach my meeting uninjured than it is for me to reach my meeting on time.*

*It may be ACCEPTABLE to delay arriving at the other side of the road by using a footbridge if the likelihood of being injured by crossing the road directly is high.*

*I analyse the situation. The footbridge is 200 metres away and will add time to my journey. The weather is good, the visibility is good and I can see that the road does not have many cars at this time.*

*I decide that walking directly across the road carries an acceptably low level of risk of injury and will help me reach my meeting on time.*

## **Plan actions to address the risks**

### **How can I avoid or eliminate the risk? How can I mitigate risks?**

*Example: I could eliminate risk of injury caused by being hit by a vehicle if I use the footbridge but I have already decided that the risk involved in crossing the road is acceptable.*

*Now I plan how to reduce either the likelihood or the impact of injury. I cannot reasonably expect to control the impact of a car hitting me. I can reduce the probability of being hit by a car.*

*I plan to cross at a time when there are no cars moving near me and so reduce the likelihood of an accident. I also plan to cross the road at a place where I have good visibility.*

### **Implement the plan – take action**

*Example:*

*I move to the side of the road, check there are no barriers to crossing. I check there are no cars coming. I continue to look for cars whilst crossing the road.*

### **Check the effectiveness of the action – does it work?**

*Example:*

*I arrive at the other side of the road unharmed and on time: this plan worked and undesired effects have been avoided.*

### **Learn from experience – improve**

*Example:*

*I repeat the plan over several days, at different times and in different weather conditions.*

*This gives me data to understand that changing context (time, weather, quantity of cars) directly affects the effectiveness of the plan and increases the probability that I will not achieve my objectives (being on time and avoiding injury).*

*Experience teaches me that crossing the road at certain times of day is very difficult because there are too many cars. To limit the risk I revise and improve my process by using the footbridge at these times.*

*I continue to analyse the effectiveness of the processes and revise them when the context changes.*

*I also continue to consider innovative opportunities:*

- *can I move the meeting place so that the road does not have to be crossed?*
- *can I change the time of the meeting so that I cross the road when it is quiet?*
- *can we meet electronically?*

## **Conclusion**

Risk-based thinking:

- is not new
- is something you do already
- is continuous
- ensures greater knowledge of risks and improves preparedness
- increases the probability of reaching objectives
- reduces the probability of negative results
- makes prevention a habit

## **Other useful documents**

ISO 31000:2009 Risk Management – Principles and guidelines

PD ISO/TR 31004:2013 Risk management - Guidance for the implementation of ISO 31000

ISO 9001:2015 Risk-based thinking - power point presentation

ISO 31010:2010 Risk management - Risk assessment techniques