

ISO 9001:2015 TRANSITIONS

6.1 – Risk Based Thinking

RISK-BASED THINKING



Andy Warhol, Eggs, 1982

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

- 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.
 - 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.

Using Risk-Based Thinking

- ISO 9001:2015 uses risk-based thinking in the following way:
 - Introduction - the concept of risk-based thinking is explained.
 - Clause 4 – the organization is required to determine its QMS processes and to address its risks and opportunities.
 - 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 – the organization is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them.
 - Clause 7 – the organization is required to determine and provide necessary resources (risk is implicit whenever “suitable” or “appropriate” is mentioned).
 - Clause 8 – the organization is required to manage its operational processes (risk is implicit whenever “suitable” or “appropriate” is mentioned).
 - Clause 9 – the organization is required to monitor, measure, analyze and evaluate effectiveness of actions taken to address the risks and opportunities.
 - Clause 10 – the 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;
 - establishes a proactive culture of improvement;
 - assists with statutory and regulatory compliance;
 - assures consistency of quality of products and services, and
 - improves customer confidence and satisfaction.
 - Successful companies intuitively incorporate risk-based thinking.

How Do I Do It?

- Identify what your risks are – it depends on context.
- Use risk-based thinking to prioritize the way you manage your processes.
- ISO 9001:2015 does not require formal risk management.
- ISO 31000 Risk management — Principles and guidelines may be a useful reference for organizations that want or need a more formal approach to risk (but its use is not obligatory).

How Do I Do It?

- Balance risks and opportunities.
- Analyse and prioritize your risks:
 - what is acceptable?
 - what is unacceptable?
- Plan actions to address the risks:
 - how can I avoid, eliminate or mitigate risks?
- Implement the plan; take action.
- Check the effectiveness of the action; does it work?
- Learn from experience; improve.

Summary of Risk-Based Thinking

- Risk-based thinking:
 - is not new;
 - is something you do already;
 - is on-going;
 - ensures greater knowledge of risks and improves preparedness;
 - increases the probability of reaching objectives;
 - reduces the probability of negative results, and
 - makes prevention a habit.

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