



Risk-Based Thinking : Is This Something New?

Risk-based thinking can be considered the fundamental change in ISO 9001:2015. Compared to ISO 9001:2008, where preventive action (PA) held a spot in the “act” phase of the plan, do, check, act (PDCA) cycle, risk now appears in the “plan” phase and at each stage thereafter. This change formalizes an idea that has been around since at least 1546, when John Heywood coined the proverb, “Look before you leap.”

Per clauses 4.1 and 4.2 of ISO 9001:2015, it is therefore reasonable that the context of an organization should be considered during the planning phase, as well as before it, together with the needs of interested parties. Based on these inputs, risk also should be considered, per clause 4.4.1 f: “address the risks and opportunities as determined in accordance with the requirements of 6.1.”

This makes us wonder: Has the standard previously not addressed risks posed to quality management systems (QMS)? Risk was always considered, but inferred and inadequately interpreted by organizations. Only now has it been systematized as a requirement. Throughout ISO 9001:2015, in clauses related to each stage of the PDCA cycle, there is a requirement to address the risk.

Can you imagine a general planning a war strategy without appreciating the risks involved, per clause 9.1.3, which requires analysis and evaluation? Perhaps this is an opportunity for the rest of the world! In real life do we not consider various risks as we send children to school, select toys, and plan expeditions? The details we go into are based on the context of what we are doing and the parties involved. Therefore, if an organization manages a simple production line to manufacture toilet rolls, the context and risk would be different than those involved in operating a nuclear plant.

But why call it “risk-based thinking” and not risk management?

ISO 9001:2015 has to be applicable across industries and to organizations of various sizes. It remains a process-based standard. Should an organization need a formal risk-management system, the standard refers to ISO 31000:2009—“Risk management.” Risk-based thinking asks that everyone in the organization think about the risk of doing, or not doing, their assigned tasks. This concept was implicit in earlier versions of ISO 9001, too, but now organizations are systematically required to understand the context (clause 4.1) and then determine risks before planning (clause 6.1).

Although the revised standard does not mention preventive action, a QMS is a preventive tool. With risk replacing preventive action, the QMS has become more effective as a philosophy. Moreover, risk no longer has a strictly negative connotation. It simply must be addressed, and where applicable, it should be taken as an opportunity for improvement. Risk input may lead to a positive and innovative idea.

As organizations transition to ISO 9001:2015, or seek to become newly certified, they must not go into “panic mode.” It’s helpful to remember that risk has always been considered in the standard, but companies are now required to be proactive rather than reactive in their considerations. With its high-level structure (HLS), ISO 9001:2015 is actually more logical, simple, user friendly, customer-focused, and aligned with modern technologies. And it’s applicable to both manufacturing and service industries.

At a very basic level, all that an organization has to do is consider these six steps:

1. Make a list of the organization’s hazards. These should be identified in various processes by process owners. Where an organization is departmentally organized, the department heads should consider these.
2. Having listed the risks, the impacts or potential harm should be listed against each risk.
3. The departmental lists can be consolidated into an organizational list under the direction of top management or a designated quality manager.
4. Evaluate each risk and its associated impact or potential hazard to assign a priority or significance number.
5. With top management’s involvement, decide how to isolate, minimize, accept, transfer, or eliminate the risk.
6. These risk-minimizing decisions then require a specific plan. Come up with proposed actions for each risk, including assigning responsibility and a

completion date for them. Process owners must also agree with top management on the frequency of monitoring the progress.

7. This can be further expanded, if necessary and within the context of the organization, by considering the likelihood of detection.

The standard asks organizations to plan to address risks but does not specify the need for a documented plan. However, a well-documented plan to address risks can only benefit an organization and add value.

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