

We're committed to helping you and your organization understand the updated requirements. This guidance document identifies the steps you should take to achieve compliance to ISO 9001:2015, and more importantly; what you don't need to do!

Clause-by- clause Interpretation

Transitioning to ISO 9001:2015

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The organization is not required to produce system maps, flow charts, lists of processes etc. as evidence to demonstrate that the processes and their sequence and interactions were determined. Such documents may be used by organizations should they deem them useful, but they are not mandatory. Graphical representation such as flow-charting is perhaps the most easily understandable method for describing the interaction between processes.

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

This is a **new requirement**. You should seek and record evidence that Top management is taking a 'hands-on' approach to the management of the QMS. Be prepared to constructively challenge Top management's commitment to the QMS. Auditing this tier of management is likely to be a new experience for many people, so it is important that you have a good understanding of management activities in order to effectively engage with them.

5.1.2 Customer Focus

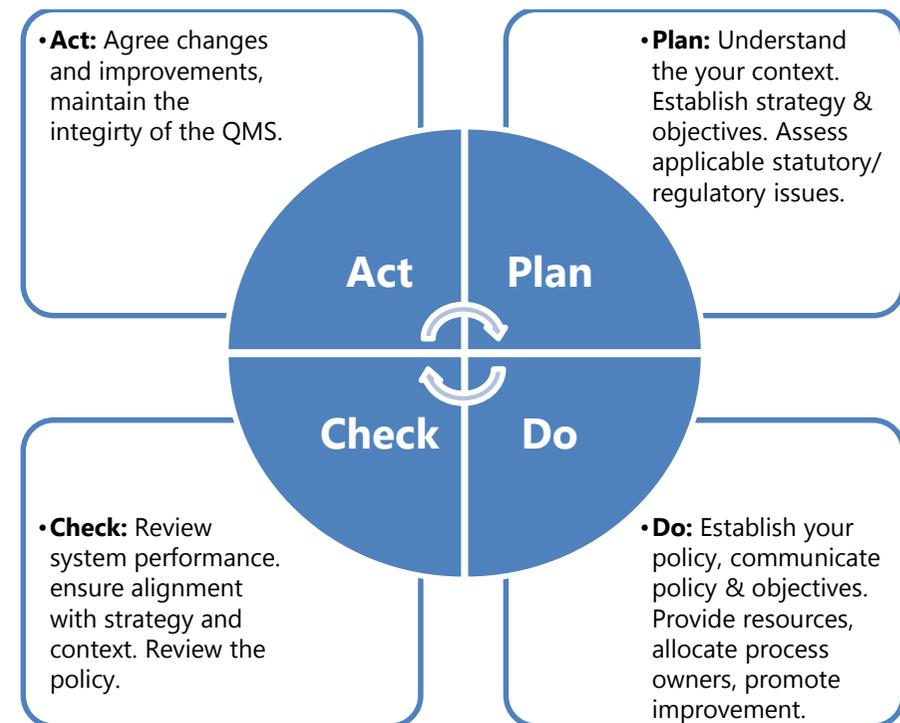
This requirement is **comparable** to the requirements of ISO 9001:2008 Clause 5.2 but now requires that Top management ensure that risks and opportunities that affect product conformity or which could affect customer satisfaction are identified and addressed.

You should seek and record evidence that Top management are ensuring that the impact of any risks and opportunities, that have the potential to affect your organization's ability to deliver products which comply with

your customer's requirements, statutory and regulatory requirements, or those which might adversely affect customer satisfaction, are identified and addressed.

You are likely to find that there is a good focus on risk, which may even be formally documented via risk assessments, but you should also ensure that opportunities are also considered.

We suggest that you use the familiar Plan-Do-Check-Act (PDCA) methodology to manage your organization's transition from the old to the new requirements using the PDCA approach:



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1. **Clause 4.4.1** requires your organization to determine the risks which can affect its ability to meet the system objectives. Risk-based thinking means considering risk quantitatively as well as qualitatively, depending on the business context.
2. **Clauses 5.1.1 and 5.1.2** require Top management demonstrate leadership and commit to ensuring that risks and opportunities that can affect the conformity of a product or service are determined and addressed.
3. **Clauses 6.1.1 and 6.1.2** require your organization take action to identify risks and opportunities, and plan how to address the identified risks and opportunities.
4. **Clause 8** requires your organization to plan, implement and control its processes to address the actions identified in Clause 6.
5. **Clause 9** requires your organization to monitor, measure, analyze and evaluate the risks and opportunities.
6. **Clause 10** requires your organization to improve by responding to changes in risk.

The adoption of risk-based thinking will, over time, improve customer confidence and satisfaction by assuring the consistency of the quality of goods and services brought on by establishing a culture of prevention and improvement.

Risk Evaluation Process

Risk evaluation should become embedded into your organization's day-to-day operations and should be undertaken at all levels throughout your organization. The overall aim of risk evaluation is to ensure that organizational capabilities and resources are employed in an efficient and

effective manner to manage opportunities and threats. Risk evaluation can be represented as a seven step, cyclical process:



Step 1: Planning

Your organization should develop and document a plan that briefly describes how and when risk, in the form of strengths, weaknesses, opportunities and threats, will be assessed, and who will be involved. This should reflect the scope (including its complexity, interfaces, etc.), policies and objectives.

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Probability Evaluation

Risk Quantification – Risks should be assessed in terms of their probability to impact on objectives:

Score	Likelihood	Description	Percentage	Probability
1	Rare	May only occur in exceptional circumstances	<0.1%	1 in 1,000
2	Unlikely	Could occur during a specified time period	1%	1 in 100
3	Possible	Might occur within a given time period	10%	1 in 10
4	Likely	Will probably occur in most circumstances	50%	1 in 2
5	Almost Certain	Expected to occur in most circumstances	>95%	1 in 1

Impact & Consequence Criteria

Risk Quantification – Risks should be assessed in terms of the consequence of their impact on objectives:

Score	Impact	Quality
1	Negligible	Quality of one or more products not on critical path does not meet quality criteria for product acceptance, but specified quality is achievable.
2	Minor	Quality of a product on critical path does not meet quality criteria for product acceptance, but specified quality is achievable.
3	Moderate	Quality of more than one product on critical path does not meet quality criteria for product acceptance, but specified quality is achievable.

Score	Impact	Quality
4	Major	Quality of a product on critical path does not meet quality criteria for product acceptance, and specified quality is not achievable.
5	Catastrophic	Quality of more than one product on critical path does not meet quality criteria for product acceptance, and specified quality is not achievable.

Risk Exposure & Control Action

The purpose of prioritising the risk is to determine the level of action needed for the identified and assessed risks.

Score	Colour	Management Control Action (MCA)
1 to 4	Very Low	No mitigation or action is required, the risk is considered ALARP. Monitor to ensure that the risk remains tolerable at this level.
5 to 8	Low	Maintain assurance that risk remains tolerable. Monitor and manage by routine procedures, unlikely to need specific application of resources (managers and key staff).
9 to 12	Medium	Tolerable if the cost of reduction would exceed the improvement gained. Mitigate by managing specific reviews and ensuring regular monitoring occurs.
13 to 15	High	Tolerable only if risk reduction is impractical or if cost is disproportionate to the improvement. Mitigate by implementing controls to reduce the risk so far as is reasonably practicable. Where this cannot happen, continual monitoring should occur.
16 to 25	Very High	Intolerable, the risk cannot be justified, expect in extraordinary circumstances. Mitigate by ceasing all related activities.

2. Relevant quality objectives;
3. Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
4. **New requirement.** The implications of not conforming to the quality management system requirements.

The awareness training does not need to follow the format of long classroom sessions. Training techniques can include short training segments supplemented with videos and hands-on demonstrations that address key elements of the QMS.

Other methods to promote and reinforce the environmental awareness training sessions include communication via electronic bulletin boards, posters, newsletters and informational meetings.

7.4 Communication

This requirement is **comparable** to ISO 9001:2008 Clause 5.5.3 – Communication but it now includes the **new requirement** to also communicate with external parties, e.g. those previously defined in Clause 4.2. You should seek evidence to confirm that your organization has identified the necessary internal and external communications that are required for the operation of the QMS. You should confirm how your organization has determined:

1. What it needs to communicate;
2. When it will communicate;
3. With whom it will communicate;
4. How it will communicate.

Internal Communications

All well as briefing employees during introductory presentations, try using a combination of other methods to promote awareness, such as posters placed on notice boards and leaflets with pay-slips, etc. Use training sessions to inform employees of the plan, how they will be expected to contribute. Issues pertaining to the quality management system that could be communicated include:

- Day-to-day operations and general awareness;
- Information on achieving objectives and targets;
- Risk and opportunities.

Auditors will wish to determine if the policies meet the intent and are understood, by interviewing personnel at all levels. Although the exact content of the policies does not need to be recited by interviewees, the awareness of the policies and how their job affects the company objectives should be determined. This does not require your employees to memorize the policies but it does mean they should be aware of it, know where it may be found and be able to paraphrase, or give an interpretation as it applies to them.

If the personnel interviewed do not know what their measurable objectives are and/or do not know what the organizational objectives are that they have a direct effect upon, the auditor would be further directed to evaluate top management's communication of the policies and objectives.

Inferred awareness through knowledge of procedures is not considered sufficient; otherwise why have the requirement in the first place? A quick and convenient way to promote and communicate the policy might be to