

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

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4.0 Context of the Organization

4.1 The Organization and its Context

The 'Context of the Organization' is a **new requirement**. You should allow additional time to prepare for each audit in order to establish a suitable understanding of the circumstances, and the market in which your organization operates. To be compliant, evidence should be obtained that proves that your organization is reviewing all pertinent internal and external issues at periodic intervals.

Although there is no requirement for documented information to define the context of the organization, your organization will find it helpful to retain the types of documented information listed below to help justify compliance:

1. Business plans and strategy reviews;
2. Competitor analysis;
3. Economic reports from business sectors or consultant's reports;
4. SWOT analysis;
5. Minutes of meetings (Management and design review minutes);
6. Process maps, tables, spreadsheets, mind mapping diagrams;

4.2 The needs and Expectations of Interested Parties

'Understanding the Needs and Expectations of Interested Parties' is a **new requirement**. You should allow additional time to prepare for each audit in order to establish a suitable understanding of the relevant interests of

relevant interested parties that impact the QMS. If this differs from the perception, you should be prepared to challenge this. Look for evidence that the organization has undergone a process to initially identify these groups, and then to identify any of their requirements that are relevant to your organization's quality management system.

You should also determine whether these groups' requirements are reviewed and updated as changes in their requirements occur, or when changes to your organization's QMS are planned.

4.3 Determining the Scope of the QMS

This requirement is **comparable** to ISO 9001:2008 Clause 4.2.2 – Quality Manual. You will need to verify that your organization's scope exists as documented information (which may be in the form of a Quality Manual) in accordance with Clause 7.5.1a. Look for confirmation that your organization has determined the boundaries and applicability of the QMS to establish its scope with reference to any external and internal issues referred to in 4.1 and the requirements of relevant interested parties referred to in 4.2.

Check that this has been produced in consideration of your organization's context and your products. You should review any exclusions previously noted under ISO 9001:2008 for ongoing suitability. Check that legacy issues which limited scope and omitted activities do not affect product conformity. Check that they are recorded and that the rationale for the exclusion is stated and justified.

4.4 The QMS and its Processes

This requirement is **comparable** to ISO 9001:2008 Clause 4 - Quality Management System and Clause 4.1 – General Requirements. You should

review how your organization has designed its process-based management system.

Existing operational procedures, work instructions and flow charts are valid examples of documented information and can be used to evidence the requirement for 'documented information to support the operation of processes is being met'.

Check that process inputs and outputs are defined and review how each the processed are sequenced and how they interact. Look for evidence that your organization has:

1. Implemented measurement criteria; (Clause 9.0)
2. Provided resources; (Clause 7.1)
3. Assigned duties/process owners; (Clause 5.3)
4. Assessed risks and opportunities; (Clause 6.1)
5. Improved its processes and the QMS; (Clause 10.0)
6. Maintained and retained documented information. (Clause 7.5.1)

Most of the requirements from Clause 4.4 are comparable to those found in ISO 9001:2008 Clauses 4.1 and 8.1 - General Requirements and Clause 8.2.3 - Monitoring and Measurement of Processes.

Based upon the extent of your organization's QMS and processes, you should seek and record evidence that your organization has maintained documented information to support the operation of its processes; and that it has retained documented information to provide confidence that the processes are being carried out as planned.

Identifying Key Processes

Key processes are steps that you go through to give the customer what they want, e.g. from order acceptance to design through to delivery. Whereas support processes do not contribute directly to what the customer wants but do help the key processes to achieve it. Support processes include often human resources, finance, document control, training and facilities maintenance, etc.

A good way to do this is to think about how workflows through your organization. Consider how the inputs and outputs to the key processes flow from one process to the next, what sub-processes might exist within it and how the support processes link in. For now, ignore the standard, in fact put it in a draw and forget it exists. Instead focus on your key processes and how the departments interface with each other.

Once you have defined the processes and interfaces; go back to the standard and determine which processes are responsible for meeting which requirements. When defining your organization's processes, think about each process and department and assign try to define those processes around the current organizational model and not around the requirements of the standard.

Certification auditors will expect to see a process model that explains the key processes of the business and how each relates and links to the others. The depth of process explanation may be as detailed as the company chooses, but should be based on its customer and applicable regulations or statutory requirements, the nature of its activities and its overall corporate strategy. In determining which processes should be determined and documented the organization may wish to consider factors such as:

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responsibility. Implement and maintain a risk management process to protect and support your organization's responsibilities.

An effective risk management approach is not only good business practice but provides organizational resilience, confidence and benefits, including:

1. Provides a rigorous decision-making and planning process;
2. Provides the flexibility to respond to unexpected threats;
3. Takes advantage of opportunities and provides competitive advantage;
4. Equips managers with tools to anticipate changes and threats, and to allocate appropriate resources;
5. Provides assurance to Top management and stakeholders that critical risks are being managed appropriately;
6. Enables better business resilience and compliance management.

Risk Management Methodology

Risk will influence every aspect of your organization's operations. Understanding the risks and managing them appropriately will enhance your organization's ability to make better decisions, safeguard assets, and enhance your ability to provide products and services and to achieve your mission and goals.

By considering risk throughout your organization 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 therefore helps to:

1. Improve customer confidence and satisfaction;

2. Assure consistency of quality of goods and services;
3. Establishes a proactive culture of prevention and improvement;
4. Intuitively take a risk-based approach.

We suggest that you use the familiar Plan-Do-Check-Act (PDCA) methodology to manage your organization's transition to risk-based thinking; using this 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.

Step 4: Response

For each risk, the risk owner must establish an appropriate level of mitigation. Control measures in addition to those already existing may be needed to achieve this level of mitigation. When a response action is completed, the risk should be reassessed (i.e. repeat Step 3) to reflect any newly introduced existing control measure.

Step 5: Review

Regular review and challenge is essential to ensure that risks are being appropriately managed, and that the risk data remains accurate and reliable, reflecting any changes in circumstances or management activities.

Step 6: Reporting

Regular reports are necessary to inform and provide assurance to Top management and other key stakeholders, that risks are being appropriately managed. Reporting must be based on current process data, which must be updated and reviewed in good time for the reporting cycle (see Step 5 above).

On occasion, it may be appropriate to escalate a risk to ensure it is assessed and/or managed by the person or party best placed to do so (able and with appropriate authority). For example where a more substantial or coordinated response is required than the current owner can authorise or implement, or where the risk severity or its effects on the wider project justify higher level assessment and/or management.

Step 7: Monitoring

Continuous systematic and formal monitoring of implementation of the risk process and outputs will take place against appropriate performance

indicators to ensure process compliance and effectiveness. Monitoring may take a variety of forms and range from self-assessment and internal audit to detailed reviews by independent external experts.

6.2 Quality Objectives and Planning to Achieve Them

The requirements of Clause 6.2.1 and Clause 6.2.2 are **comparable** with the requirements of ISO 9001:2008 Clause 5.4.1 – Quality Objectives. You should seek and record evidence that your organization's quality objectives are consistent with the quality policy, and that they are relevant to product and service conformity, and the enhancement of customer satisfaction.

Quality objectives should be measurable and are likely to have their own metrics by which levels of attainment can be ascertained. Check that the quality objectives are communicated throughout the organization and that they are updated to ensure relevance to changing business needs.

You should seek and record evidence that effective planning was undertaken in support of the organization's quality objectives and their achievement. You should ensure that this planning activity takes into considerations of Clause 6.2.1, as well as the following points:

1. Identification of processes, resources, and skills needed to achieve quality;
2. Identification of suitable verification criteria at appropriate stages;
3. Compatibility of design, production, inspection and testing;
4. The confirmation of criteria of acceptability for all features and requirements;