

ISO 9001:2015 KEY CONCEPTS EXPLAINED



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This document outlines the of the key concepts within ISO 9001:2015. It also explains variations from the previous version of the standard ISO 9001:2008.

A major change within ISO 9001:2015, and to all management system standards, is the incorporation of the high level structure of clause sequence, common text and common terminology defined in ISO document Annex SL.

Annex SL enables full alignment of all ISO management system standards, which will help streamline management systems and make the audit process more efficient.

STRUCTURE OF ISO 9001:2015

The structure of ISO 9001:2015 follows the high level structure defined in Annex SL:

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

KEY CONCEPTS

High level changes to all management system standards

The most significant changes in the 2015 standard are in Clauses 4, 5 and 6 above, i.e. Context of the organisation, Leadership and Planning, but there are many others throughout the standard.

Context of the Organisation

This is a new concept and relates to the external factors and conditions that affect an organisation. Examples could include governance, regulation, sector, stakeholders and shareholders to name but a few.

Tip: The context will influence the type and complexity of management system needed.

Leadership

There is an explicit requirement for top management to demonstrate leadership and engage directly with the system. This is an enhanced requirement relating to management.

Tip: Top management is expected to be "hands on" and to ensure that the quality policy and quality objectives are consistent with the overall strategy and context at the organisation. This is new territory for ISO 9001 audits, and more audit time is expected to be devoted to discussions with the organisations leaders.

Planning

Planning is a new term introduced to the high level structure, with a requirement to address risks and opportunities and to carefully plan changes within the management system. This is an enhanced requirement.

Tip: Risks and opportunities, for example, could relate to the use of electronic systems within the management system. Introducing such systems would require change and transition arrangements, which should be planned within the management system.

Support

This new term builds upon the 2008 requirements for competence, awareness (now extended to include persons under the organisation's control, not just employees) and communication. This is an enhanced requirement.

Tip: With the increasing use of outsourced providers, this requirement reminds us that this resource must be managed effectively just as internal providers are managed.

Performance evaluation

This has similar themes to the existing standard, but with a new emphasis on evaluation in addition to the current requirement to measure and analyse.

Tip: Evaluation is the interpretation of results and analysis. This is not new to managers but is made explicit in the standard for the first time. Processes may be well defined and effective, but do they yield optimum results? This may be a new challenge for internal audits.

Summary of Specific Changes to ISO 9001

Process Approach

An enhanced emphasis on the process approach is incorporated in the standard, with a requirement for the organisation to determine its processes.

Risk Based Thinking

The concept of risk has been introduced, with a requirement to determine risks opportunities and plan accordingly. Although all management systems, in particular ISO 9001, are fundamentally about managing risk, this is the first time risk actually gets an explicit mention.

CONCLUSION

ISO 9001:2015 is much less prescriptive than previous versions, and incorporates more business management terminology and concepts. Documentation requirements are much less prescriptive and left more to the organisation to judge its own needs.

The standard is written for the benefit of organisations, not auditors. Auditors will need to understand and recognise the extent and type of evidence that is acceptable in order to confirm compliance to the 2015 requirements.

ISO 9001:2015 auditors will be engaging in dialogue with business leaders, seeking understanding and explanations from them about policy, strategy and quality objectives to ensure these are compatible.

The audit experience from the client perspective is likely to be very different.

WE ARE HERE TO HELP

We will help you understand the changes, interpret the new concepts and act on the implications.

Keep updated with the changes at www.nqa.com/change

Please get in touch if you have any questions – call **08000 522424**.



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