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Article – Sept 2014

Clauses of the new ISO 9001:2015 standard

ISO (the International Standards Organisation) has a strategy to create a common approach to management system standards. This common approach will apply to all certification standards, and therefore includes the ISO 9001 Quality standard. Part of this approach includes a common high-level clause structure.

Individual standards may add additional "discipline-specific" requirements as required. ISO believes that this common approach will increase the value of such standards to users. It will be particularly useful for those organisations that wish to implement an IMS (integrated management system) to address the requirements of two or more standards.

The following table illustrates the difference between the high-level clause structure of ISO 9001:2008 and ISO 9001:2015.

ISO 9001:2008	ISO 9001:2015
0. Introduction	0. Introduction
1. Scope	1. Scope
2. Normative References	2. Normative References
3. Terms and Definitions	3. Terms and Definitions
4. Quality Management System	4. Context of the Organization
5. Management Responsibility	5. Leadership
6. Resource Management	6. Planning
7. Product Realization	7. Support
8. Measurement, Analysis and Improvement	8. Operations
	9. Performance Evaluations
	10.Improvement

The following table illustrates the clause structure of ISO 9001:2015 in more detail and in the context of the PDCA cycle – starting at clause 4 (the first clause specifying a requirement).

PLAN				DO	CHECK	ACT
4. Context of the organisation	**5. Leadership**	**6. Planning for the QMS**	**7. Support**	**8. Operation**	**9. Performance evaluation**	**10. Improvement**
4.1 Understanding the organization and its context	5.1 Leadership and commitment	6.1 Actions to address risks and opportunities	7.1 Resources	8.1 Operational planning and control	9.1 Monitoring, measurement, analysis and evaluation	10.1 General
4.2 Understanding the needs and expectations of interested parties	5.2 Quality policy	6.2 Quality objectives and planning to achieve them	7.2 Competence	8.2 Determination of requirements for products and services	9.2 Internal audit	10.2 Nonconformity and corrective action
4.3 Determining the scope of the QMS	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.3 Awareness	8.3 Design and development of products and services	9.3 Management review	10.3 Continual improvement
4.4 QMS and its processes			7.4 Communication	8.4 Control of externally provided products and services		
			7.5 Documented information	8.5 Production and service provision		
				8.6 Release of products and services		
				8.7 Control of nonconforming process outputs, products and services		

The following is a brief commentary on those clauses:

Context of the organization

4.1 Understanding the organization and its context.

A new requirement; One of several that might suggest a greater union between the QMS and wider business planning activities. Requires organisations to ascertain, monitor and review both internal and external issues that are relevant to its purpose and strategic direction, and have the ability to impact the QMS and its intended results.

4.2 Understanding the needs and expectations of interested parties.

A broadening of scope beyond just customers. Requires the organisation to determine “the relevant requirements” of “relevant interested parties” e.g. a person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity.

4.3 Determining the scope of the QMS.

The scope statement must state the products and services covered.

4.4 The QMS and its processes.

A major change that specifies a number of factors to be considered when planning the processes that make up the QMS. Although a process-planning approach has been previously expressed in earlier standards, this greatly reinforces the requirement.

5 Leadership

5.1 Leadership and commitment.

Greater emphasis is placed on the role of top management. Requires top management to “demonstrate leadership and commitment”, and suggests that a more hands-on approach is expected.

5.2 Quality policy.

Policy requirements are enhanced. A requirement is introduced that the quality policy is appropriate to the context of the organization, and that it is applied throughout the organization.

5.3 Organizational roles, responsibilities and authorities.

The requirement for a Management representative is no longer specified. The duties previously assigned to that role may now be assigned to any role or split across several roles.

6 Planning for the QMS

6.1 Actions to address risks and opportunities.

A major change introduced to require a risk-based approach. In addition to this clause, reference to the terms ‘risk’ and ‘opportunity’ are made throughout the standard.

6.2 Quality objectives and planning to achieve them.

Requirements for objective planning are tightened up. An objective should include a description of who is responsible, what is the target, when is it planned to be achieved. Progress must be monitored. Also, requires objectives to be set for relevant processes.

6.3 Planning of changes.

The clause lists items to be considered in change management.

7 Support

7.1 Resources.

7.2 Competence.

7.3 Awareness.

There is an expansion of application from “personnel” to “persons doing work under the organization’s control”.

7.4 Communication.

Now includes external communication about the QMS.

7.5 Documented information.

New requirement to determine, make available, and maintain knowledge.
No requirement for quality manual or procedures.
“Documents”, “Documentation” and “Records” are combined to become “Documented information”.
Requirements are expanded to mention issues such as confidentiality, access, and (data) integrity. This suggests an adoption of information security considerations in recognition of the increasing use of electronic documents/data.

8 Operations

In a welcome change of terminology, the rather clumsy ‘Product realization’ becomes ‘Operations’
8.1 Operational planning and control.
8.2 Determination of requirements for products and services.
8.3 Design and development of products and services.
This may be interpreted that more organizations do some form of design and development.
8.4 Control of externally provided products and services.
An expansion of scope - from just suppliers to also include other external providers of products and services
Purchasing” and “Purchased product” become “Externally provided products and services”.
8.5 Production and service provision.
An expansion on previous requirements e.g. documented information to specify intended results, and to determine the nature and extent of any post-delivery (after-sales) activities.
8.6 Release of products and services.
8.7 Control of nonconforming process outputs, products and services.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation.
There is a new requirement to obtain information relating to customer views and opinions of the organisation.
9.2 Internal audit.
Audit schedule must take customer feedback into account.
9.3 Management review.
Expanded requirements for management review inputs or agenda.

10 Improvement

10.1 General.
10.2 Nonconformity and corrective action.
Specific reference to preventive action is removed.
Now includes an additional requirement to record the nature of nonconformities.
On discovering a nonconformity, an explicit requirement is introduced for organisations to determine whether other similar nonconformities actually exist, or could potentially exist.
10.3 Continual improvement.

Wrap up

The above is intended as a brief introduction to the new clause structure, and our initial thoughts on their requirements. We have highlighted what we consider to be the most significant changes. Others may well have a different view on them. Readers should also be aware that there may be further changes in the final draft, and then the actual international standard. Although the wording may well be adjusted by the time that ISO 9001:2015 is finally published, we can feel fairly certain that the principal changes – the common structure and terminology, more defined process approach, and consideration of risk – will remain.

Keeping informed

Newsletters

Qudos will provide further updates on the new ISO 9001 and changes to other standards via our regular newsletters. You may sign up for our newsletter by clicking on the link at our web site: www.qudos-software.com.

Quality Manager Toolkit

Our award-winning toolkit already contains material relevant to the forthcoming ISO 9001 – such as templates and samples for Process Plans. Over the coming weeks and months, this will be regularly updated to include new articles, guidance material, planning tools, sample policies, documents, and other resources. The Quality Manager toolkit is available in Qudos Club and Qudos 3 software – see below.

Qudos Club

The online resource library for compliance and risk management is constantly being updated with new content for Quality, Safety, and Environmental management. To join, or for existing member login, go to www.qudosclub.com

Qudos 3 software

The current version of Qudos 3 already supports most requirements of the new standards - with further enhancements also in development. Contact info@qudos-software.com.

Free Seminars

Qudos are holding a series of free seminars on the new ISO 9001. The first of these has already taken place. If you are interested in attending a seminar, or if you have any comments or questions, we would be pleased to hear from you. Contact info@qudos-software.com.

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