Revision of ISO 9001 *Quality Management Systems – Requirements*

Frequently Asked Questions

When will the new ISO 9001 be published?

The international standard ISO 9001:2008 *Quality management systems – Requirements* is currently being revised. The draft international standard (ISO/DIS 9001:2014) has now been released for comment. The revised ISO 9001 is planned to be released in late 2015.

Why is ISO 9001 being revised?

This is the first major revision of ISO 9001 since 2000.

The key drivers for the revision were:

- ISO has developed a common framework for ISO management system standards in order to enhance alignment between them
- the ISO committee conducted a user survey and analysed the input on potential new or changed requirements
- there is a need to reflect current business practices and technology
- ISO 9001 provides a generic set of quality management system (QMS) requirements but improvement is needed to make it more readily applicable, particularly to the service sector.

What is ISO/DIS 9001:2014?

ISO/DIS 9001:2014 *Quality management system – Requirements* is the ISO draft international standard (ISO/DIS) that is released for public comment. The ISO/DIS was prepared by a working group of the responsible committee ISO/TC 176/SC 2. Member bodies of this committee, including Standards New Zealand, submit comments and vote in the ballot whether to accept the ISO/DIS for revision to a final draft international standard (ISO/FDIS). The ballot period will conclude on 7 October 2014.

The ISO/DIS is a major opportunity for the public to propose changes to the draft standard. The ISO/FDIS will be distributed for ballot and further comments in early 2015 but only editorial and clarification changes are likely to be accepted at this stage.

Where can I obtain a copy of ISO/DIS 9001:2014?

The ISO/DIS is currently available for purchase directly from Standards New Zealand. Note that ISO/DIS 9001:2014 is copyright-protected by ISO.

The ISO/DIS is also available at the main city libraries in Auckland, Wellington, Christchurch, and Dunedin.

How do I comment on the ISO/DIS?

Comments on the ISO/DIS or issues raised in this article can be submitted either:

a) In the **comments and queries form** (go back to the main web page for a link) or
b) Using the **ISO comments template** (go back to the main web page for a link). We recommend that people making detailed comments use this template since it allows for reference to line numbers and clause numbers as well as submitting reasons for suggested changes and suggested alternative text.

Public comments need to be submitted to Standards New Zealand prior to 8 September 2014 to allow time to prepare the New Zealand submission.

Can I ask questions about the ISO/DIS?

To ask questions about the ISO/DIS, please use the **comments and queries form**.

Standards New Zealand will post timely replies to queries.

How will New Zealand comments on the ISO/DIS be prepared?

The Standards New Zealand international review group (IRG) responsible for quality management standards will prepare New Zealand's submission on the ISO/DIS, taking account of submitted comments. Where there is disagreement, the committee is responsible for reaching an agreed position.

The Convenor of the IRG, Diane Baguley, is a member of the ISO Working Group responsible for drafting the ISO 9001 revision. She will advise on matters such as where suggested changes fall outside the design specification for the revision and the use of consistent terminology in submitted alternative text.

The submission will reference all comments to line numbers as well as clause numbers. Where changes are suggested, alternative text needs to be submitted.

What are the main changes to the standard?

The main changes to ISO 9001 are listed below (see also **Can you explain the main contents of the ISO/DIS?**).

- There are changes to the structure and terminology used in the standard (see below **Why has the structure been changed?**)
- The term 'products and services' is used throughout to cover all categories of outputs to customers
- A full list of definitions is currently included in ISO 9001 since ISO 9000 is not yet revised
- There are some new requirements, most making implicit requirements more explicit
- Many requirements have been reworded for clarification or to apply consistent language
- There is no provision for excluding requirements of the standard for certification – where a requirement can be applied within the determined scope, it must be applied
- There is a new requirement to determine issues related to the context of the organisation
- There is a new requirement to determine risks and opportunities as a basis for planning but no requirement for formal risk management

- Requirements for leadership are strengthened
- There is no requirement for a ‘management representative’ but responsibilities and authorities for management the quality management system need to be allocated
- There are additional requirements for control of changes to the quality management system
- The term ‘documented information’ replaces ‘documents and records’
- There is no requirement for a ‘quality manual’
- There is a new requirement for controlling organisational knowledge
- The requirements for monitoring and measuring ‘resources’ (rather than ‘equipment’) is more flexible for application to different monitoring and measurement situations
- The terms ‘external provider’ and ‘external provision’ are used to define requirements for purchasing, suppliers, and outsourcing
- There is no specific requirement for preventive action.

Why has the structure been changed?

ISO has developed a framework to enhance alignment between its management system standards, including:

- major clause headings
- high level text
- common terminology definitions.

The ISO framework is available on the ISO website as Appendix 2 to Annex SL *High level structure, identical core text and common terms and core definitions for use in Management Systems Standards* in the ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2014.

Working groups drafting new or revised management system standards use the framework and add discipline-specific clauses and text. Changes to the ISO framework are avoided except where considered essential.

Using this framework for the ISO 9001 revision has changed the order of some clauses and introduced some new requirements compared to ISO 9001:2008. Framework headings and text are identified in the ISO/DIS by a blue font (see below **What is the blue text and can it be changed?**).

What is the blue text and can it be changed?

A blue font is used in the ISO/DIS to identify headings, definitions, and text provided in the ISO framework. The blue font is used only to facilitate review – it will not be used in the published version ISO 9001:2015.

Changes to the ISO framework (blue text) will only be considered where necessary to reflect specific quality management requirements or other compelling reasons such as translatability. One example is that the term ‘outcomes’ of a system has been changed to ‘results’ because in some languages ‘output’ and ‘outcome’ would normally be translated by the same word. Changes such as this are likely to be adopted in the next revision of the ISO framework.

Changes to the blue text of a ‘wordsmithing’ nature will not be incorporated in this revision of ISO 9001.

Do we need to use the new structure and terminology in our QMS?

Changes in structure and terminology in the revised ISO 9001 do not need to be reflected in an organisation's quality management system (QMS) documentation.

Whether in this or previous versions, the structure of clauses in ISO 9001 is not intended as a model for documenting an organisation's policies, objectives, and processes.

As to terminology, organisations can use the terms that best suit their operations. For example, an organisation might want to continue to distinguish 'documented procedures' and 'records'. However in the current technology environment this distinction can be unclear. Hence ISO adopted the term 'documented information' in the framework.

What documentation is required under the ISO/DIS?

The risk-based approach used in drafting the ISO/DIS means that there should be more flexibility for organisations to decide what documentation they need.

There is no requirement for a 'quality manual'. For many organisations this term has become outdated in modern management practice. The term has probably also contributed to the tendency of some organisations to follow the clauses of ISO 9001, rather than the logic of their management system, in documentation. Organisations can, of course, continue to use the term 'quality manual' if they choose.

The ISO/DIS uses the term 'documented information' to cover both 'documented procedures' and 'records' in ISO 9001:2008. Where such information is needed to implement the quality management system, the requirement is to 'maintain' documented information. Where it is produced as a result of processes, the requirement is to 'retain' documented information. The distinction between 'maintain' and 'retain' is simply a matter of the requirements making sense in context.

Can you explain the main contents of the ISO/DIS?

0 Introduction
The Introduction includes the process approach, the Plan-Do-Check-Act cycle, and risk-based thinking.

> ***Comment:*** Managing processes within a coherent system has been the basis for quality management system requirements since ISO 9001:2000. Guidance on the process approach and the PDCA cycle has been enhanced. Risk-based thinking has been implicit in previous versions of ISO 9001 but is now more explicit. The Introduction clarifies that there is no requirement for a formal risk management process.

1 Scope
The scope of the standard is essentially unchanged. However the 'exclusions' Clause 1.2 in ISO 9001:2008 is removed.

> ***Comment on 'exclusions':*** Clause 4.3 deals with determining the scope of the organisation's quality management system (QMS). This says that where a requirement within the determined scope can be applied, then it must be applied. There is a further safety net by stating that if any requirement cannot be applied, this must not affect the organisation's ability or responsibility to ensure conformity of products and services.

2 Normative references
At present there are no normative references because ISO 9000 *Quality management systems – Fundamentals and vocabulary* has not yet been revised to the ISO/DIS stage.

3 Terms and definitions
At present this clause has a full list of definitions since a revised ISO 9000 is not yet released. In the ISO/DIS there are many pages of definitions and comments can be made on individual definitions. However the inclusion of definitions, and how many should be included, will be reviewed once the alignment with the revision of ISO 9000 is clarified.

4 Context of the organisation
This is a new clause. It has subclauses on understanding the organisation and its context, understanding the needs and expectations of interested parties, determining the scope of the quality management system, and the quality management system and its processes.

> ***NEW on 'context':*** The organisation has to 'determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s)' as a basis for planning the quality management system. The organisation has to 'monitor and review' this information – in small organisations this is likely to be combined with management review activities.
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> ***NEW on 'interested parties':*** The organisation has to determine 'the interested parties that are relevant to the quality management system' and 'the requirements of these interested parties that are relevant to the quality management system'. Note that this requirement is limited to 'relevant' interested parties and the 'requirements' (not needs and expectations) of those parties. The subclause title 'understanding the needs and expectations of interested parties' is retained to align with other management system standards.

5 Leadership
Covers leadership and commitment, customer focus, quality policy, and organisational roles, responsibilities, and authorities.

> ***Comment:*** There is more emphasis than previously on leadership and commitment. The term 'management representative' is not used.

6 Planning for the quality management system
Includes actions to address risks and opportunities (determined under clause 4), quality objectives, and planning of changes.

> ***NEW on addressing risks and opportunities:*** The organisation is required to determine the risks and opportunities that need to be addressed, based on the issues and requirements referred to in clause 4. Actions taken need to be proportionate to their potential impact. While this is a new requirement, a risk-based approach has been implicit in previous versions of ISO 9001. Addressing risks and opportunities should enable organisations to 'tune' the requirements of ISO 9001 to their particular circumstances. There is no requirement for formal risk management or a documented risk management process.
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> ***Comment on 'planning of changes'*:** ISO 9001:2008 clause 5.4.2 (b) required that the integrity of QMS be maintained when changes are made. The requirements have been made more

explicit in a new clause 6.3 defining what the organisation needs to consider including, for example, the availability of resources. There is also a requirement in clause 8.5.6 on control of changes in production and provision processes. The requirement for control of design and development changes is retained. How these three clauses work together, and whether there is unnecessary duplication, needs to be considered.

7 Support

Covers resources (including people, infrastructure, the environment for operation of processes, monitoring and measurement resources, and organisational knowledge), competence, awareness, communication, and documented information.

***Comment on 'documented information'*:** Much of this clause will look familiar to current users apart from a change of terminology to 'documented information' covering 'documented procedures' and 'records' in past ISO 9001 editions.

NEW requirement on 'organisational knowledge': There is a requirement to 'determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services' and to maintain and make available that knowledge to the extent necessary.

8 Operation

Covers processes for providing products and services: operational planning and control, determination of requirements for products and services, design and development, control of externally provided products and services, production and service provision, release of products and services, and control of nonconforming process outputs, products, and services.

***Comment on clause 8.3 'design and development'*:** The requirements for design and development are not greatly changed. Consideration was given to simplifying the requirements to make them more readily applicable to the service sector. However the ISO/DIS reflects a majority view that making the requirements too generic would lose value to many current users.

***Comment on clause 8.4 'externally provided products and services'*:** this clause applies to all forms of external provision – purchasing, outsourcing, and so on – in order to be applicable in a more complex business environment.

***NEW on clause 8.5.6 'control of changes'*:** there is a requirement for control of changes during production and service provision.

9 Performance evaluation

Includes monitoring, measurement and evaluation, internal audit, and management review.

10 Improvement

Includes general improvement requirements, nonconformity and corrective action, and continual improvement.

Comment on improvement: there is no clause on 'preventive action'. This is because one of the key purposes of a quality management system is to act as a preventive tool.

There are three informative Annexes:

Annex A: Clarification of new structure, terminology, and concepts (a useful guide to current users of ISO 9001)

Annex B: Quality management principles (the revised edition of the principles)
Annex C: The ISO 10000 portfolio of quality management standards.

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