Quality Management System standard ISO 9001 is undergoing significant revisions. Currently at Draft International Standard (DIS) stage, the new ISO 9001:2015 is due to be published in September 2015.

This bulletin discusses the anticipated changes proposed to the structure and the content of the standard, and what these changes will mean for organisations and their quality management systems.

Guidance on how to understand the changes and manage the transition process will help to ensure that your organisation is compliant and prepared for assessment against the new standard.

Intended for:
- Organisations with ISO 9001:2008 certification
- Organisations seeking ISO 9001 certification
- Organisations implementing ISO 9001 systems

Contents
- Introduction
- Current status of ISO 9001:2015
- Summary of key proposed changes to ISO 9001:2015
- What happens next?
- Training and support

For more detailed advice, contact BM TRADA at the address shown on the back page.
Introduction

The Quality Management System standard ISO 9001 is being revised and will become ISO 9001:2015. ISO anticipates that ISO 9001:2015 will be published in September 2015. This revision of ISO 9001 is set to be significant as a result of fundamental changes to both the structure and contents of the standard.

All management system standards are subject to a periodic review process, normally every 5 years, to ensure that the standard:

- continues to meet the needs and demands of interested parties
- maintains relevance in the marketplace as the diversity of users increases, taking account of industry and technological changes
- provides a consistent foundation for future needs and requirements of a quality management system standard.

ISO 9001:2015 will adopt the Annex SL high level structure framework. Annex SL provides the framework for management system standards. The Annex SL structure will ensure that going forward all new or revised management system standards will have the same overall 'look and feel' with regards to:

- high level structure
- identical core text
- common terms and core definitions.

As a result, it will be easier for organisations to implement an integrated management system.

Current status of ISO 9001:2015

ISO 9001:2015 is currently at the Draft International Standard (DIS) stage. This is the first publicly available draft of the standard and provides an indication of what requirements might be included in the final version.

It is important to note that this is not the final version of the standard and further changes may be made before final publication.

After October 2014 (the end of the period for public consultation on the DIS), all comments received will be analysed and those accepted will be worked into the Final Draft International Standard (FDIS) which is expected to be published in July 2015. Once ISO 9001:2015 FDIS is published only minor editorial changes can be made, so the standard requirements will be finalised at this point.

Summary of the key proposed changes to ISO 9001:2015

Note that the following information is based upon the proposed changes in the ISO 9001:2015 DIS and as such is subject to change in the final version of the standard.

High level Annex SL structure

The standard will adopt the high level Annex SL structure that will contain the following clauses:

1. Introduction
2. Scope
3. Normative references
4. Terms and definitions
5. Context of the organization
6. Leadership
7. Planning
8. Support
9. Operation
10. Performance evaluation
11. Improvement

Changes to clauses and their content

The anticipated changes to the contents of these clauses and the likely implications for organisations are detailed in Table 1.
Table 1: Clause revisions in ISO 9001:2015

<table>
<thead>
<tr>
<th>Proposed change</th>
<th>Details and impact</th>
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<tbody>
<tr>
<td><strong>Leadership</strong></td>
<td>Clause 5, previously ‘Management Responsibility’, is being replaced with ‘Leadership’. Top management will be required to be actively involved in the operation of the quality management system. The removal of all references to the role of ‘management representative’ reinforces a need to see the quality management system embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.</td>
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<td><strong>Context of the organisation</strong></td>
<td>A new clause and sub clauses are being introduced relating to the context of the organisation. Organisations will be required to identify explicitly any internal and external issues that may impact their quality management system’s ability to deliver its intended results. They will also have to develop a methodology to understand the needs and expectations of ‘interested parties’ – those individuals and organisations that can affect, be affected by, or perceive themselves to be affected by, the organisation’s decisions or activities.</td>
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<td><strong>Scope of the quality management system</strong></td>
<td>Greater emphasis has been placed on the definition of scope of the quality management system compared to the previous version of the standard. The scope sets the boundaries for, and identifies the applicability of, an organisation’s quality management system. Clause 4.3 requires scope to be determined with consideration to the organisation’s context.</td>
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<td><strong>Process approach requirements</strong></td>
<td>The process approach that was promoted by ISO 9001:2008 will be an explicit requirement of DIS ISO 9001:2015 (clause 4.4), which sets out the specific requirements designed to enforce the adoption of a process approach.</td>
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<td><strong>Risks and opportunities</strong></td>
<td>Reference to preventive action is removed from the DIS and replaced with ‘actions to address risks and opportunities’. Organisations will be required to determine, consider and, where necessary, take action to address any risks or opportunities that may impact (either positively or negatively) their quality management system’s ability to deliver its intended outcomes, or that could impact customer satisfaction.</td>
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<td><strong>Products and services</strong></td>
<td>The term ‘product’ is being replaced by ‘products and services’. By including explicit reference to services as well as products, the standard reinforces that ISO 9001:2015 is applicable to all suppliers, not just those that are manufacturing or supplying products.</td>
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<td><strong>Control of externally provided products and services</strong></td>
<td>‘Purchasing’ (clause 7.4) will be replaced with clause 8.4 ‘Control of externally provided products and services’. The clause will address all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organisation, or by any other means. Organisations will be required to take a risk-based approach to determine the type and extent of controls appropriate to each external provider and all external provision of products and services.</td>
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<tr>
<td><strong>Documented information</strong></td>
<td>Requirements for a documented quality manual, documented procedures and records will be removed and replaced with the term ‘Documented information’. This is information that the organisation will be required to keep, control and maintain. How it wishes to record this information is up to the organisation itself. This provides a more flexible approach to how companies document their arrangements for quality management.</td>
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<tr>
<td><strong>Non conforming processes</strong></td>
<td>Control of non conforming product (clause 8.7) will now include non conforming processes in addition to outputs and services. This will require organisations to evaluate when processes are non conforming to planned arrangements and, if appropriate, to investigate the reasons why and take action to prevent recurrence of the problems.</td>
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**Proposed change** | **Details and impact**
--- | ---
Terms and definitions | These are being brought into the body of the ISO 9001:2015 standard. ISO 9001:2008 terms and definitions currently reside in a separate standard, ISO 9000:2005.

Annexes | ISO 9001:2015 will have three informative annexes. Annex A will give clarification on the new structure, terminology and concepts underpinning the DIS, while Annex B will provide refreshed Quality Management Principles, which are drawn across from ISO 9004. Annex C will detail related quality management system standards from the ISO 10000 series. These are designed to provide assistance to organisations seeking to establish or improve their quality management performance.


**What happens next?**

The migration process to the revised standard starts now. Companies should start to familiarise themselves with the proposed structure and requirements of the (DIS) ISO 9001:2015.

Internal planning and communication should start now, and include the preparation required to modify existing quality management systems as necessary. Top management needs to understand its new obligations and internal auditors will need to undergo training to equip themselves to assess against the new standard.

**Transition process**

It is anticipated that ISO 9001:2015 will be published in September 2015. Once the standard is published, a three-year transition period is expected. As such, companies with existing ISO 9001 certification must be certified against the ISO 9001:2015 standard by September 2018. After this date, certificates against ISO 9001:2008 will no longer be valid.

The current ISO 9001:2008 standard will be recognised and can be audited against at any time during the three-year ISO 9001:2015 transition period. However, in the last year of the transition period, all certified companies should be in a position to be audited against the ISO 9001:2015 standard. This will ensure timely transition.

If you are currently implementing a management system to ISO 9001:2008 and you are expecting to be certified shortly, it is recommended that you continue implementation as you will still have a full three years to transition to the new standard once it is published.

However, you should familiarise yourself with the changes to the new standard, including the high level Annex SL structure, so that you can keep this in mind when implementing your system.

Official transition timescales and guidance will be published as soon as the requirements become available.

![ISO 9001:2015 transition timeline](image-url)
Training and support
BM TRADA is providing a series of transition workshops and training programmes on how to prepare and implement the revised requirements in line with the timelines for continued accredited certification.

For further information see www.bmtrada.com/training

If you have any questions regarding the new ISO 9001:2015 standard please contact your local BM TRADA office.

Acknowledgements
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Further help
BM TRADA offers further information on ISO 9001:2015 compliance

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<td>t: 01494 569671</td>
<td><a href="http://www.bmtrada.com/training">www.bmtrada.com/training</a></td>
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Further information about Annex SL

ISO/DIS 9001 standard
http://bookshop.bmtrada.com

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<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EU Timber Regulation (EUTR)</td>
<td>CE marking: from 1st July 2013</td>
</tr>
<tr>
<td>A summary of requirements and obligations</td>
<td>Implications of the Construction Products Regulation</td>
</tr>
</tbody>
</table>

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