

DIS 9001 2014

UNDERSTANDING THE DRAFT
INTERNATIONAL STANDARD

EXECUTIVE SUMMARY



The CQI and IRCA remain convinced that those leading, managing and auditing quality management systems will need to revise their current thinking and work in different ways in order to maintain organisational compliance in the future.

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Executive summary

The CQI has direct access to TC 176, the Technical Committee responsible for updating the current version of the standard, ISO 9001:2008. As such, we have a specific insight into not only the content of the new version but also the intention behind it.

There has been some debate internationally about the implications of the proposed changes for both quality and audit professionals. Some national bodies regard the changes as insignificant, taking the view that ISO 9001:2015 simply introduces a number of requirements that were previously implied in ISO 9001:2008 but that were not mandated.

The CQI and IRCA do not share this position. We remain convinced that those leading, managing and auditing quality management systems will need to revise their current thinking and work in different ways in order to maintain organisational compliance in the future.

What has led us to this conclusion?

The changes incorporated into DIS 9001:2014 can essentially be divided into those that have arisen as a result of the adoption of Annex SL as the basis for the standard and those that have arisen as a result of the desire to amend current quality management specific requirements.

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In the preface to *IRCA briefing note: Annex SL* (available free of charge on both the CQI and IRCA websites), we describe the introduction of Annex SL as “the most important event since ISO 9001”. Its adoption has implications for all those using management system standards, be they standard writers, management system implementers, auditors or training providers.

Life should become easier for management system standard writers. They can now concentrate their efforts on developing the discipline-specific requirements that will be focused on Clause 8 – Operation.

Will this lead to shorter development times for ISO standards? Hopefully the answer is yes, but we will need to wait to see if this proves to be the case in practice.

Implementers of management systems should find life easier too. Those seeking to introduce multiple management systems (eg Quality, Environmental, Health and Safety) will have less work to do because in future, the core requirements of these will be identical. This will simplify both the initial implementation and the ongoing maintenance of such systems.

For management system auditors, the adoption of Annex SL means that there will be a generic set of requirements that need to be assessed when conducting management system audits, irrespective of the discipline that is actually being audited.

As a result of the above, we expect to see training organisations start to offer generic management system auditing courses as alternatives to their currently offered discipline-specific ones. Those auditors wishing to achieve sector-specific registration would then complete secondary modules to top up their earlier generic training.

The IRCA has already advised IRCA-Approved Training Organisations to adopt such an approach when designing auditor transition training courses, and is committed to reviewing its core Foundation, Internal Auditor, Auditor/Lead Auditor and Auditor Conversion courses later this year.

While the adoption of Annex SL will ultimately benefit all those who make active use of management system standards, in the short term there will be challenges for those concerned with establishing, implementing, managing or auditing against ISO 9001.

The impact is likely to be greatest for practitioners and auditors rather than the organisation itself, as many of the new and enhanced requirements are things that organisations and businesses should be doing already – for example, understand the needs and expectations of stakeholders. The difference will be that these activities will have to be transparent and demonstrable, so organisations may need to make some activities more evident than they currently are.

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Management
Responsibility
now becomes
Leadership



For those organisations already living by the spirit of ISO 9001:2008, the transition to ISO 9001:2015 should prove relatively straightforward. Whereas, for those organisations that are simply complying with the requirements of ISO 9001:2008 at the most basic level, work will be required to address the current culture of the organisation.

Culture can be described as “the way things are done around here” – however, this culture will have to change as a consequence of the adoption of Annex SL as the basis for ISO 9001:2015. This includes the behaviours of everyone connected with the quality management system, and, in particular, of those operating at the most senior level within an organisation.

Culture change can be notoriously difficult to effect and it is primarily for this reason that the CQI and IRCA have taken the position that ISO 9001:2015 represents such a significant revision.

ISO 9001:2015 will now make us do the things ISO 9001:2008 always wanted us to do but did not specify due to resistance from some parties.

Summary of principal changes – ISO 9001:2008 to ISO 9001:2015

- **The new draft standard adopts the high-level structure and terminology of Annex SL.** Annex SL was developed to ensure all future ISO management system standards would share a common format, irrespective of the specific discipline to which they relate.
- Annex SL prescribes a high-level structure, identical core text, and common terms and definitions. This means that even when requirements are essentially unchanged between ISO 9001:2008 and DIS 9001:2014, these are frequently found under a new clause/sub-clause heading.
- Clause 5, previously “**Management Responsibility**”, now becomes “**Leadership**”. Top management are required to demonstrate that they engage in key quality management system activities as opposed to simply ensuring that these

activities occur. This means that there is a need for top management to be actively involved in the operation of their quality management system. The removal of all references to the role of “management representative” reinforces a desire to see quality management systems embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure.

- Two new clauses (4.1 and 4.2) are 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 must also 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.
- DIS 9001:2014 places a **greater emphasis on the definition of scope** of the quality management system than ISO 9001:2008 does. Scope sets the boundaries for, and identifies the applicability of, an organisation’s quality management system. Clause 4.3 requires scope to be determined in consideration of the organisation’s context.
- While ISO 9001:2008 promoted the **adoption of a process approach** when developing, implementing and improving the effectiveness of a quality management system, clause 4.4 of DIS 9001:2014 sets out specific requirements designed to enforce its adoption.
- **References to preventive action have disappeared** – however, the core concept of identifying and addressing potential mistakes before they happen very much remains. DIS 9001:2014 now talks in terms of **risk and opportunities**. Organisations must evidence that they have determined, considered and, where necessary, taken 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.

- The term **“product”** will be replaced by **“products and services”**. Previously, the inclusion of services as products was implicit. By including explicit reference to services, the standard writers are attempting to reinforce that 9001 is applicable to all suppliers, not just those that provide physical goods.
- DIS 9001:2014 clause 10 recognises that incremental (continuous) improvement is not the only improvement profile. Improvement can also arise as a result of periodic breakthroughs, reactive change or as a result of reorganisation. Thus, the title of this clause is now “Improvement” (ISO 9001:2008 8.5.1 referred to “Continual improvement”).
- The phrase **“externally provided products and services”** replaces “Purchasing”. Clause 8.4 addresses 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 are 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 goods and services.
- **References to a documented quality manual, documented procedures and to quality records have been removed**. Instead, throughout DIS 9001:2014 there are specific references to “Documented Information”. This is information that the organisation is required to keep, control and maintain. How it wishes to record this information is up to the organisation itself; formats and storage methods are not prescribed in the DIS.
- There has been a conscious attempt to revisit the wording of the standard with a view to making the requirements easier to understand and to aid its translation.
- Where requirements were previously implied, the wording of the standard has been amended to make them explicit. Understanding the organisation and its context, and the adoption of a process-based approach, are perhaps the most significant examples but these are not the only instances, as a detailed examination of the clauses confirms.

**Annex SL
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and definitions.**

- **Terms and definitions have now been brought into the body of DIS 9001:2014.** ISO 9001:2008's terms and definitions reside in a separate standard, ISO 9000:2005. However, for DIS 9001:2014, terms and definition are contained within the requirements standard itself. This has significantly increased the size of the DIS and will consequently also impact its pricing.
- DIS 9001:2014 has **three informative annexes**. Annex A provides clarification on the new structure, terminology and concepts underpinning the DIS, while Annex B provides refreshed Quality Management Principles, which are drawn across from ISO 9004. Annex C details related quality management system standards from ISO's 10000 series. These are designed to provide assistance to organisations seeking to establish or improve their quality management performance.
- **Renumber existing QMS documentation** to correspond to the new clause references. Although organisations may choose to carry out a renumbering exercise, it is down to each to determine whether the benefits gained from renumbering will exceed the effort involved in actioning the change. However, reference needs to be made to compliance with 9001:2015, if the organisation wishes to demonstrate compliance to this Standard.

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Key changes you do not need to make

Organisations do not need to:

- **Remove their management representatives.** While there is no requirement in DIS 9001:2014 for a management representative, this does not prevent organisations from choosing to retain this role if they so wish. Be aware, however, that some of the duties traditionally assigned to the management representative by top management will, in future, need to be undertaken directly by top management themselves.
- **Throw out their Quality Manuals and Documented Procedures.** While DIS 9001:2014 sets out no requirement for organisations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, then there is no need for it to be withdrawn.
- **Restructure their management systems** to follow the sequence of requirements as set out in the DIS. Providing all of the requirements contained in the DIS are met, the organisation's system will be compliant.
- **Refresh existing documentation** to use the new terms and definitions contained within DIS 9001:2014. Once again, organisations are free to make the judgement as to whether this effort would be worthwhile. If organisations are more comfortable using their own terminology, eg "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.



This is an Executive Summary of the full version of the CQI report **DIS 9001:2014 – Understanding the Draft International Standard**. To purchase the full report, please visit www.thecqi.org/DISreport



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The Chartered Quality Institute (CQI)

The CQI is the chartered body for quality management professionals. It exists to benefit the public by advancing education in, knowledge of and the practice of quality in industry, commerce, the public sector and the voluntary sectors.

The International Register of Certificated Auditors (IRCA), a division of the CQI, is the leading professional body for management system auditors.

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