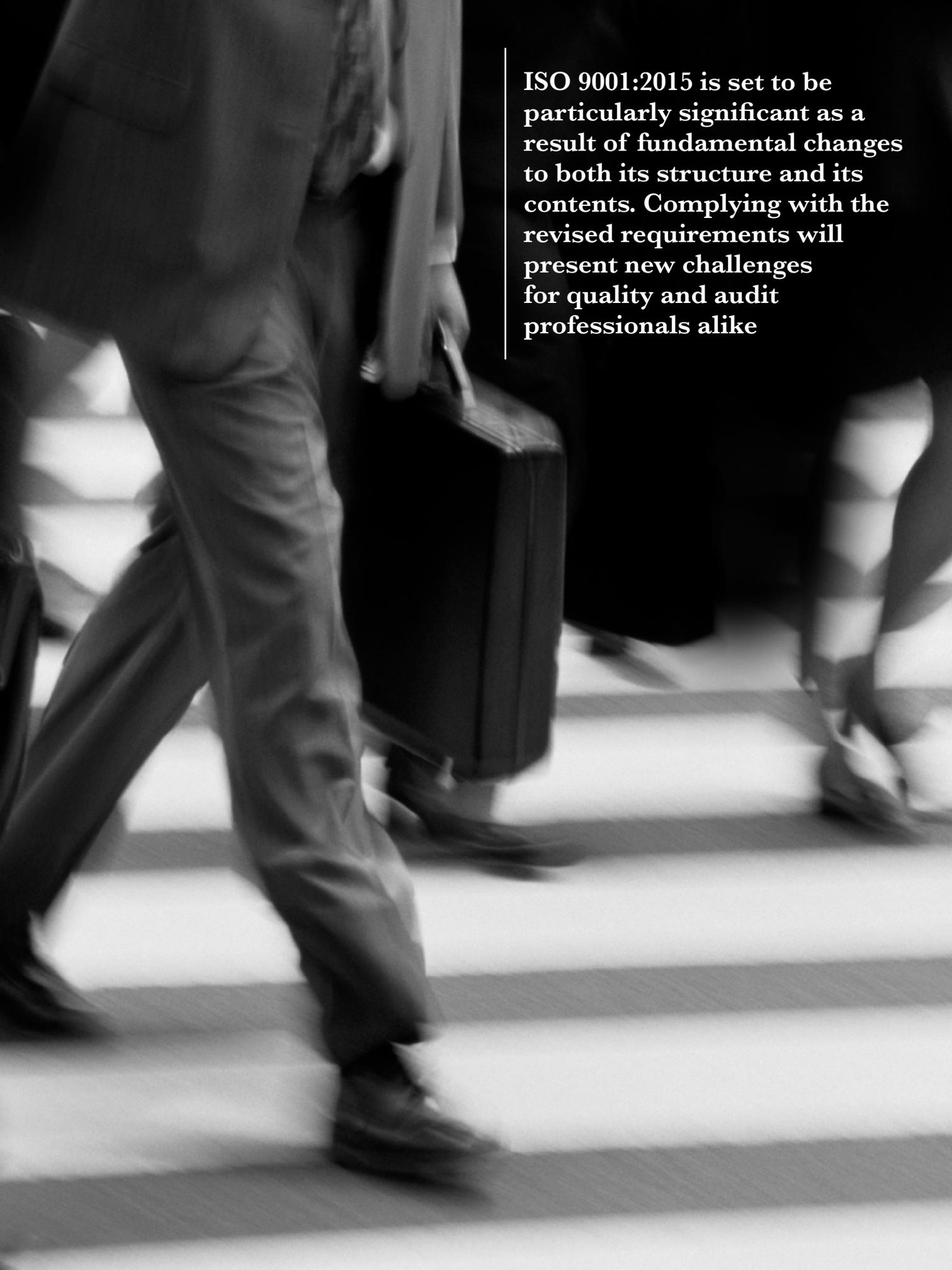




ISO 9001: 2015

Understanding the International Standard



ISO 9001:2015 is set to be particularly significant as a result of fundamental changes to both its structure and its contents. Complying with the revised requirements will present new challenges for quality and audit professionals alike

Introduction

For more than 20 years, the International Organization for Standardization (ISO) has regularly conducted a survey that is designed to provide an insight into the worldwide adoption of ISO's management system standards.

The latest edition of the survey (2014) reveals a healthy growth across the board for all management system standards as at the end of 2013, with a total of 1.6 million certifications globally. Of these, 1.1 million were against ISO 9001:2008, exceeding the total issued against all other ISO management system standards combined by a factor of 3 to 1.

Accordingly, any revision of ISO 9001 will have global implications based simply on numbers alone. The 2015 release, however, is set to be particularly significant as a result of fundamental changes to both its structure and its contents. Complying with the revised requirements will present new challenges for quality and audit professionals alike.

The International Standard, ISO 9001:2015, was published in September 2015.

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

There has been some debate internationally about the implications of the proposed changes for both quality and audit professionals. Some 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 organizational compliance.

What has led us to this conclusion?

The changes incorporated into ISO 9001:2015 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 improve current quality management specific requirements.

In the preface to the CQI and IRCA Annex SL Briefing Note (available free of charge to CQI and IRCA members), 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 6 – Planning and Clause 8 – Operation. Will this lead to shorter development times for ISO standards?

Hopefully 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 (for example, Energy, Environmental, Health and Safety) will have less work to do because in future, the structure and 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 being audited.

As a result of the above, we expect to see training organizations 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.

IRCA has already advised IRCA-Approved Training Organizations to adopt such an approach when designing auditor transition training courses, and has reviewed and re-issued its core Foundation, Internal Auditor, Auditor/Lead Auditor and Auditor Conversion courses.

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 9001:2015. The impact is likely to be greatest for practitioners and auditors rather than the

organization itself, as many of the new and enhanced requirements are things that organizations should be doing already – for example, understanding the needs and expectations of stakeholders (referred to as “interested parties”).

The difference will be that these activities will have to be transparent and demonstrable, so organizations may need to make some activities more evident than they currently are.

For those organizations already operating by the spirit of ISO 9001:2008, the transition to ISO 9001:2015 should prove relatively straightforward. Whereas, for those organizations 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 and operation of the organization.

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 organization.

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

- ANNEX SL The new standard adopts

the format 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 ISO 9001:2015, these are frequently found under a new clause/sub-clause heading.

- **LEADERSHIP** 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 the requirement to see quality management systems embedded into routine business operations, rather than operating as an independent system in its own right with its own specialist management structure and processes.
- **CONTEXT** Two new clauses (4.1 and 4.2) are introduced relating to the context of the organization. The organization is required to identify explicitly any external and internal 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” (or stakeholders) – those individuals and organizations that can affect, be affected by, the organization’s decisions or activities.

- **SCOPE** ISO 9001:2015 places a greater emphasis on the definition and content of the scope of the quality management system than ISO 9001:2008 did. The scope sets the boundaries for, and identifies the applicability of, an organization’s quality management system. Clause 4.3 requires scope to be determined in consideration of the organization’s context.
- **PROCESS APPROACH** 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 ISO 9001:2015 sets out specific requirements considered essential to the adoption of a process approach.
- **RISK-BASED THINKING** References to preventive action have disappeared. However, the core concept of identifying and addressing potential mistakes before they happen very much remains. ISO 9001:2015 now talks in terms of risk and opportunities. The organization must evidence that they have determined, considered and, where necessary, taken action to address any risks and opportunities that may impact (either positively or negatively) on their quality management system’s ability to deliver

its intended results or that could impact customer satisfaction.

- **SERVICES** The term “product” has been replaced by “products and services”. Previously, the inclusion of services as products was implicit. By including a reference to services, the standard writers are attempting to reinforce that ISO 9001:2015 is applicable to all organizations, not just those that provide tangible products.
- **IMPROVEMENT** ISO 9001:2015 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 was “Continual improvement”).
- **EXTERNAL PROVISION** The phrase “externally provided processes, products and services” replaces “Purchasing” and “Outsourcing”. 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 organization, or by any other means. An organization is 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.
- **DOCUMENTATION** References to requirements for a documented quality manual, documented procedures and to quality records have been removed. Instead, throughout ISO 9001:2015 there are specific references to “documented information”. This is information that the organization is required to control, maintain and retain. How it wishes to record this information is up to the organization itself; formats and storage methods are not prescribed in the standard.
- **CLARITY** 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 organization and its context, the adoption of a process approach, and risk-based thinking are perhaps the most significant examples but these are not the only instances, as a detailed examination of the clauses confirms.
- **TERMINOLOGY** As in the 2000 and 2008 editions, the terms and definitions remain in the separate standard - ISO 9000:2015. However, ISO has made available the terms and definitions available online: www.iso.org/obp
- **ANNEXES** ISO 9001:2015 has two informative annexes. Annex A provides clarification on the new structure, terminology and concepts underpinning

the standard. Annex B details the other International Standards on quality management and quality management systems developed by ISO/TC 176. These are designed to provide assistance to an organization seeking to establish, implement, improve or audit their quality management performance.

Organizations do not need to:

- **REMOVE** their management representatives. While there is no requirement in ISO 9001:2015 for a management representative, this does not prevent the organization from choosing to retain this role if they so wish. Be aware, however, that some of the responsibilities traditionally assigned to the management representative by top management will, in future, need to be undertaken directly by top management themselves.
- **RELEGATE** their Quality Manuals and Documented Procedures to the dustbin. While ISO 9001:2015 has no requirement for the organization to have and use either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn.
- **RENUMBER** or rename existing QMS documentation to correspond to the new clause references. Although an organization may choose to carry out a renumbering/renaming exercise, it is down to them to determine whether the benefits gained from renumbering/renaming will exceed the effort involved in actioning the change.
- **RESTRUCTURE** their management systems to follow the sequence of requirements as set out in the standard. Providing all of the requirements contained in the DIS standard are met, the organization's system will be compliant.
- **REFRESH** existing documentation to use the new terms and definitions contained within ISO 9001:2015 and ISO 9000:2015. Once again, the organization is free to make the judgement as to whether this effort would be worthwhile. If the organization is more comfortable using their own terminology, for example, "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.

Interpretation

The interpretations of requirements contained within this document are those of the CQI and IRCA – other organizations may interpret the requirements of ISO 9001:2015 differently. As such, this document should not be viewed as the definitive reference source for this International Standard. Indeed, only documentation sourced by ISO/TC 176 can fulfil this purpose.

Note: neither the CQI nor IRCA are permitted to reproduce the exact wording of the standard due to copyright restrictions. Those individuals who need access to the exact wording should make provision to acquire a legal copy of the Standard from a reputable source.

Learn more

CQI and IRCA members can download our full report for detailed technical analysis, practical recommendations and independent expertise. quality.org/members-area