

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 core 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, or perceive themselves to 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) 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 explicit 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 reorganization. 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. ISO has also made the terms and definitions available online: <http://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.

Key changes you do not need to make

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 duties (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/rename exercise, it is down to them to determine whether the benefits gained from renumbering/rename 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 standard are met, the organization’s system will be compliant.
- **REFRESH** existing documentation to use the new terms and definitions contained within 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, e.g. "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.

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Further information on this and the details of the new Standard can be found via the links below:

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