

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

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- 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 organization. Organizations 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 organizations that can affect, be affected by, or perceive themselves to be affected by, the organization'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 organization's quality management system. Clause 4.3 requires scope to be determined in consideration of the organization'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. Organizations 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 products.**
- **DIS 9001:2014 clause 10 recognizes 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 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 organization, or by any other means. Organizations 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 products 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 organization is required to keep, control and maintain. How it wishes to record this information is up to the organization 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 organization 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.
- 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 definitions 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 organizations seeking to establish or improve 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 DIS 9001:2014 for a management representative, this does not prevent organizations 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 organizations to hold 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 existing QMS documentation to correspond to the new clause references. Although organizations 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 the change. However, reference needs to be made to compliance with 9001:2015, if the organization wishes to demonstrate compliance to this standard.**
- **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 organization's system will be compliant.**
- **Refresh existing documentation to use the new terms and definitions contained within DIS 9001:2014. Once again, organizations are free to make the judgment as to whether this effort would be worthwhile. If organizations are more comfortable using their own terminology, e.g. "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.**