ISO 9001:2015 – Introducing the changes

Although the new version brings some significant changes, the good news is that many of the requirements we have become familiar with in previous versions of the ISO 9001 standard will remain the same.

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.

This revision of ISO 9001 is significant as a result of fundamental changes to both the structure and contents of the standard.

There are now seven principles instead of the eight in the 2008 revision, but the essence is the same. The new version has 10 instead of the eight clauses in the old version, and instead of six mandatory procedures, there are now six mandatory documents that don't have to be in the form of a procedure. This can be little confusing at the beginning, but the intention was to provide more liberty in documenting the Quality Management System.

There are some new requirements, but the most significant are Context of the organisation (Clause 4) and Actions to address risks and opportunities (Clause 6.1). The idea behind these new requirements is to make the QMS (Quality Management System) a part of everyday business activities, and vice versa. Of course, some old requirements are history now: Quality Manual (not mandatory), management representative, and preventive actions are no longer part of ISO 9001.

Changes to the clauses and their content

Change	Detail and impact
Leadership	Clause 5, previously 'Management Responsibility', has been 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.
Context of the organisation	A new clause and sub clauses have been introduced relating to the context of the organisation. Organisations are required to identify explicitly any internal and external issues that may impact their quality management system's ability to deliver its intended results. They 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.
Scope of the quality management system	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.
Risks and opportunities	Reference to preventive action has been removed 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.
Products and services	The term 'product' has been 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.

Change	Detail and impact
Control of externally provided products and services	Purchasing' (clause 7.4) has been replaced with clause 8.4 'Control of externally provided products and services'. The clause 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 products and services.
Documented information	Requirements for a documented quality manual, documented procedures and records has been 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.
Non-conforming processes	Control of non conforming product (clause 8.7) will now include non-conforming processes in addition to outputs and services. This requires 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.

How The Ideas Distillery can help

The Ideas Distillery will undertake the following programme of work to successfully transition you to the 2015 standard:

1) Undertake an Internal Audit to the new 2015 standard. The first step is to identify areas of your current system which may need updating.

2) Define the context of your organisation through a Context Review. This is a new requirement and requires special attention, because it provides the basis for your new Quality Management System.

2) List all interested parties through a stakeholder analysis. Although it belongs to the same clause as Context of the organisation, it is something new and should be considered carefully. Having all interested parties and their expectations identified will help the organisation to adjust its strategic direction.

3) Review the scope of the QMS. We need to consider the existing scope of your QMS, since its credibility depends on it.

4) Demonstrate leadership. The requirements are almost the same as those for management commitment in the previous version, but the new version puts even greater emphasis on the leadership. We must demonstrate leadership through taking

accountability for the QMS, providing resources, and establishing a Quality Policy and quality objectives.

5) Align QMS objectives with the company's strategy. Your QMS must be compatible with strategic direction of the company, quality objectives must aim in the same direction as other activities in the company. The plans for achieving the objectives must be created, which is a requirement of the new version.

6) Assess risks and opportunities. According to the new version, risks and opportunities must be addressed. They focus on the ability of organisation to achieve intended results, but also on other parts of the system such as context of the organisation and compliance obligations. After the assessment of risks and opportunities, there should also be some plans for addressing them.

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