ISO 9001 is an international standard that states specific requirements for a Quality Management System (QMS). Organizations that achieve ISO 9001 certification are able to demonstrate their ability to provide quality product or services to their customers. ISO 9001 was first published in 1987 by International Organization for Standardization and the latest revision of the standard was published in September 2015. It can be used by any small or large organization regardless of the nature of business. It is based on key principles of quality management that include customer focus, involvement and motivation of top management, continual improvement and process approach.

According to Nigel Croft, the Chair of ISO subcommittee that prepared the revised standard, the changes in 2015 revision are more of an “evolutionary rather than revolutionary” process. The 2015 version is also designed to integrate with other management systems to enable organizations to easily and effectively achieve multiple standard certifications. The focus from documents and records in the previous version has now shifted more towards managing the processes, thus making the revision less prescriptive. This has been achieved by applying risk-based thinking to the process approach and deploying Plan-Do-Check-Act cycle at all the levels of the organization.

According to the acting Secretary General of ISO Kevin McKinley, “The world has changed, and this revision was needed to reflect this. Technology is driving increased expectations from customers and businesses. Barriers to trade have dropped due to lower tariffs, but also because of strategic instruments like International Standards. We are seeing a trend towards more complex global supply chains that demand integrated action. So organizations need to perform in new ways, and our quality management standards need to keep up with these expectations. I am confident that the 2015 edition of ISO 9001 can help them achieve this.”

Analyzing some of the changes in 2015 revision, we see that Clause 4 is the first substantive clause in your ISO management system. First, let’s take a look at how many requirements you now need to comply with. On the face of it, Clause 4 is now a bit simpler, with the number of “shall” statements reducing from 28 to 24. But dig a bit deeper, and it’s not so simple.

A whole section in the old 9001:2008 standard – Clause 4.2 that states documentation requirements – has now shifted to Clause 7.4 in the new standard. This accounts for 8 distinct requirements on its own. Stripping these out, we can see that Clause 4 has actually increased the number of requirements from 20 to 24.

There’s some big changes in Clause 5 to get up to speed with in the transition from ISO 9001:2008 to the new 2015 revision. Here’s a summary:

* Clause 5 in the old standard has now morphed into two clauses in ISO 9001:2015 – a new clause 5 on Leadership and a new clause 6 on Planning.
* Clause 5.5.3 on Internal Communication has moved to become Clause 7.4 in the new standard.
* Clause 5.6 on Management Review has now moved to become clause 9.3 in the new standard

At the same time the total number of requirements has increased from 32 to 54. Adjusting for the movement of clauses, it has increased from 26 to 54. In other words, its complexity has more than doubled. Auditors will be looking for evidence that these requirements are being met. How best to do this? Some will say that this demands a change in organizational culture for many of us. More immediately, we should also take the simple steps, including:

* Publishing key documents e.g. policy documents on our public web sites or internal intranets
* Mapping out a clear timetable for all aspects of our quality program
* Keeping lightweight records of key internal communications relating to quality

The concept of Risks and Opportunities is introduced for the first time in clause 5.1.2 b and clause 6.1, with 6 specific new risk-related requirements brought in. In the old standard, risk was mentioned just once in Clause 0.1a, with no “shall” requirement, so nobody took much notice of it. With ISO 9001:2015, you must be able to demonstrate an understanding of business risks and how they could impact on your ability to meet customer requirements. This is best demonstrated to an auditor by compiling a simple Risk Register.

In effect, Risks replace the Preventive Action concept in ISO 9001:2008. The meaning of Preventative Action vs Corrective Action was a source of confusion for many people, so this is a simplifying step that I welcome.

To meet these new requirements, it is recommended to take the following steps:

* Create a simple Risk Register
* Assign your risks to categories
* Create a simple scoring system for Risks
* Periodically, evaluate the highest scoring risks for management action
* Devise and implement a treatment and control plan

According to ISO 9001, your QMS should meet each requirement in order for it to comply with the standard. A requirement can only be excluded if it is not applicable to your organization and if you can ensure that its absence does not affect the quality of your product or service in terms of compliance. How an organization chooses to meet ISO requirements depends upon many factors and varies according to the organizational structure, context, objectives, processes, risks, products, services, etc. After developing a QMS that meets the requirements of ISO 9001, you can ask a certification body or registrar to conduct an audit of your system. After the audit comes out clear, the certification body issues a certificate that your organization meets all the requirements of ISO 9001.