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Why the latest version of the ISO9001 Quality Management Standard is good news for business

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Executive Summary

The ISO 9001 international Quality Management Standard has provided a framework for business measurement and improvement for nearly 30 years, the latest 2015 edition continues this overall system with significant new additions to enhance the achievable outcomes.

This paper outlines what the key differences are and how they can have a positive impact upon your organisation and its future development.

Background

Most people are familiar, to a greater or lesser extent, with the name at least of the ISO 9001 Quality Management System (QMS), but is there an understanding of where the requirements originated or how the thinking behind the standard has significantly changed over the past 30 years?

The origins of ISO 9001, whilst not exactly lost in the mists of time, stem from a combination of influences built up from the AQAP's (Nato Allied Quality Assurance Programme), US mil-Q-9858 and UK def-stan (defence standard) stipulations amongst others.

Prior to the ISO9001:2015 issue in September 2015 there had been a regular development of the standard

- ISO 9001:1987. The first edition based directly upon the BS 5750 requirements
- ISO9001:1994. A series of defined procedures, 20 in all that governed the way that certain steps should be followed in the operation of an organisation
- ISO9001:2000. A radical step-change document, calling for the identification, mapping and control of all key processes across the organisation and documentation / procedures to support and sustain the said procedures. The associated ISO 9002 and 9003 standards for the registration of non-manufacturing organisations were removed, with all registrations reverting to ISO 9001, with appropriate exclusion clauses.

- ISO9001:2008. A relatively minor set of tweaks and adjustments to the 2000 edition.

ISO9001:2015. Still process based but adopts the App SL standardised formatting, with the concepts of Organisation, Leadership and Risk Based Thinking (RBT). The very poorly understood term Preventive Action is superseded by RBT. The standard requires procedures and documentary evidence as appropriate to the scale and complexity of the business.

From this start-point with Quality, the International Standards Organisation (ISO) has produced a wide range of other framework standards covering the areas of:

The Environment (ISO14001), Occupational Health & Safety, (OHSAS 18001 soon to be ISO45001), Data Security (ISO 27001) and Business Continuity, (ISO22301) amongst others.

Some of these have featured a format similar to the ISO 9001 pattern and others have not. This can then present a challenge for organisations seeking to implement a resource efficient combined management system for two or more of these disciplines. Hence the evolution of Appendix SL, a standard template set of requirements for all future management system standards and already implemented for 9001, 14001, 27001 and 22301 with the new Health & Safety standard ISO45001 to come in mid 2016

Acceptance

In overall terms the concept and practice of a globally recognised, universal common standard for quality has been enormously successful with registrations achieved by in excess of 1.1 million companies, the leaders in terms of number being:

- China over 340,000
- Italy 168,000+
- Germany 55,000+
- Japan near 46,000
- India 41,000
- UK over 40,000.

A notably low number is then the USA at 33,000, but in general the major global industrialised nations are well represented, with Italy a real stand-out over representation.

In terms of total global registrations there has been a significant reduction dating from 2008 and is a clear knock-on effect of the banking induced crisis and recession that affected the majority of the industrialised economies. China did not totally avoid this impact, but the strength and growth of this economy resulted in a strong level of resilience in the ISO registrations present.

The de-registration of a business from the ISO regime does not necessarily mean the end of the positive influences and monitors that the systems provides. The framework if internally maintained will continue to furnish the organisation with data and information to enable review, analysis and then continued improved to be effected. A business lacking an independent registration does however have a far more difficult task to evidence the state and progress of their framework systems. Many vendor assessment processes and methodologies discount any claim of adherence to a standard unless it is accompanied by the accrediting body itself holding an independent certification body status (granted by UKAS for the UK). This is

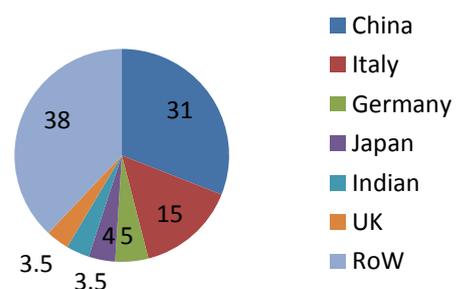
the major shortcoming of the self-certification option.

An area of growth in the past ten years has been the sector specific schemes, built upon the foundations of ISO 9001, but then adjusted for the detailed needs of that market. These now include Aerospace (AS9100), Automotive (TS16949), Rail (IRIS) and Medical (ISO14385).

I believe that it is quite likely that these sector focused standards may well proliferate and be strengthened by the nature of the 2015 edition of ISO9001 with its' demonstration rather evidence based methods.



ISO9001 by Country Percentages



The Positive News Regarding ISO 9001:2015

There are numerous factors that suggest that the 2015 edition of ISO 9001 will provide a positive influence on Quality Systems and business performance in general. The most positive factors in my view are:

Appendix SL. A standard format of 10 sections to be adhered to by all new and updated management standards, accompanied by sections of core text that is then applicable in all cases. The standard sections provide for a ready recognition of what type of issue is under review and in particular facilitates the merging of standards into more efficiently managed Combined Management Systems (CMS).

In the case of ISO 9001 the core text accounts for circa 55% of the requirements, whilst Section 8 - Operation adds the bulk of the custom, standard-specific requirements. It should be noted that much of this Section 8 - Operation has been lifted from the previous Section 7 - Product Realisation in the 2008 edition.

Note the change in section title from Product Realisation to Operation, a move to make the standard less overtly focused upon manufacturing and more easily applicable into all types and sizes of organisation.

Context. A new area that brings in a point of fundamental analysis and consideration before undertaking the balance of the requirements of the standard. In basic terms, who is impacted by the organisation and who has influence and needs to place upon the body? Answers to these points then set up the initial focus upon which are the responsibilities, expectations and hence risks faced by the organisation and, conversely, what are the opportunities for development, growth and improvement. With at least a good view on these issues then the organisation can plan upon firmer foundations and a surer view of the way forward.

Leadership. Good leadership from ‘the boss’ and / or the senior team in an organisation has been shown repeatedly to be a critical factor in the successful ongoing development of an organisation. This has always been the case and was required in the earlier version of the standard, however the 2015 edition carries far more emphasis and importance on the role that leaders need to show and demonstrate.

Demonstrate is a key word in the 2015 edition and obviously evidence (information, data and records) can and does meet this requirement. It is however acceptable to provide a discursive demonstration of compliance with the standard. This is an area of subjectivity that should be avoided, or minimised as best possible, easing the task for all parties involved.

Planning (Risk-Based Thinking). In many ways this is the nub of the 2015 edition, bringing a new way of thinking to business decisions formally into the management framework.

Risk is inherent in all aspects of a business. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the quality management system.

In previous editions of ISO 9001, a clause on preventive action was separated from the whole. By using risk-based thinking the consideration of risk is integral. It

becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Risk-based thinking is something we all do automatically in everyday life. Risk-based thinking needs to be considered from the beginning and throughout the system, making preventive action inherent to planning, operation, analysis and evaluation activities

Knowledge in the Organisation. A new, and relatively low-key addition to the standard, but potentially one of the most vital issues for the continued success and development of an organisation and, in specific terms, a management standard registration. However critical knowledge locked into one person, or a small team can easily be lost due to a whole raft of issues and can damage or even destroy the future of a business. What is critical to your organisation in terms of knowledge; who holds this information and how can it be secured, passed on or recorded?

Areas of Concern / Uncertainty

In a nutshell, these all relate to the sharply increased levels of subjectivity introduced, as compared to the clear evidential based requirements of the 2008 and earlier editions.

There are numerous references to effectively demonstrating an issue. What does this mean? Obviously having firm evidence to support and corroborate a statement is an excellent demonstration of the situation, however it is not mandatory or apparently necessary to have such evidence and a statement of performance / conformance should be satisfactory. But, one man's demonstration may well be not sufficient proof or convincing to another, particularly an external auditor.

As Richard Green of the CQI (Chartered Quality Institute) stated in the paper

ISO9001:2015 Understanding the International Standard. 'The auditors will need help'.

In order to smooth the progress of audits and to accurately and effectively get across the position of the organisation, and the senior team in particular, then evidence of the application of Risk-Based Thinking (RBT) and consideration of the context of the business will be most beneficial to all parties. It will also facilitate monitoring and review of the significant risks and opportunities.

It is precisely for this reason that PerformancePlus developed the RAMP product that succinctly details risks and opportunities, ranks them, details the control and improvement factors and provides a log for ongoing monitoring and continuous improvement.

A consensus will also be required with regards to the documentation and records commensurate with the scale and complexity of the organisation. Most likely there will be guidance from UKAS with regards to this issue in the not too distant future.

Summary

We are now working with a significantly changed ISO 9001 standard, some would say a radically revised document and although a few concepts are significantly different, the reality is a further evolution of a well proven framework system. Organisations that have adopted the philosophies behind the standard in addition to the required elements and processes have benefited to a much greater extent than those that merely give a token adherence to the stipulations. This has always been the case, but the 2015 edition of ISO 9001 amplifies the level of benefit that are there to be tapped into.

By formally considering both the opportunities and the risks faced by the organization in all key areas and then monitoring how these change and develop, potentially as a result of planned actions then a greater awareness will result.

Once more awareness is the key phrase with regards to the context of the organisation, knowing what is demanded by regulation and legislation and further, what is desired by all of the stakeholders in the business. With this information on-board there is a way to make better informed decisions and to have more foresight in the planning activities.

One of the most pertinent requirements added to the 2015 edition relates to the management and retention of knowledge. All groups should recognise that knowledge locked into the brains of one or a few individuals make the organisation extremely vulnerable to the loss, by whatever means of the said person(s).

So by applying all of the previous good practice in term of process standardisation, a strong customer focus and an ingrained system of continuous improvement, allied to the new gospel of context, risk and opportunity management an organisation has a more comprehensive tool-kit with which to drive the business forward.

Work will be required to fully master the new requirements and to integrate them into the operating systems of the business, but the rewards will be a more rounded and better informed framework to guide you forward in the ever more competitive world that we operate in.

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