Reflections on 3 Decades of "ISO 9000"

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INTRODUCTION

ISO's Technical Committee TC176 (Quality Management and Quality Assurance) was formed in 1979, and its early work culminated in the publication in 1986 of ISO 8402 (the quality vocabulary standard; subsequently replaced by ISO 9000), and the first version of the ISO 9000 series of standards in 1987. The standards have evolved significantly over the last 3 decades and are now used extensively around the world not only as a basis for certification, but also to provide a solid foundation for organizations to incorporate whatever quality tools and methodologies are the most appropriate and effective for them to be able to achieve their sustainable development objectives, within their own specific business context.

Unfortunately, for some people, the first thing that comes to mind when management system standards are mentioned is the outdated (and near-sighted) philosophy of "write down what you do, then do what you wrote" that was associated with the first versions of ISO 9001 (and its predecessor BS5750) in the late 1970's and 1980's. This created a mentality that management systems should focus on documented procedures for everything and provide evidence in the form of records. Many argued that innovation and organizational agility were incompatible with "ISO 9000" and quite often changes were not implemented by using the excuse "our ISO system will not allow us to do that!" Nothing could be farther from the truth - if a management system is properly implemented and is truly being put to good use by the organization, it should be results-focused and facilitate innovation and change in a structured, disciplined and agile manner.

EVOLUTION OF THE ISO 9000 STANDARDS

ISO 9001 is undoubtedly the best-known standard of the ISO 9000 series and is used extensively for third party certification in global supply chains for products and services. The prime focus of ISO 9001 is to provide confidence to customers that an organization understands their needs and expectations and is able to consistently provide products and services that meet their requirements. But that is not enough for an organization to be successful in today's competitive and demanding market. There are of course other considerations, such as the ***efficiency*** of the organization, the needs and expectations of interested parties other than the direct customer, and consideration of a wider range of factors that are important to ensure its long-term (sustained) success. These wider perspectives are addressed in the ISO 9004 Guidelines standard "Quality of an organization – Guidance to achieve sustained success", recently updated and with the latest version published in April 2018.

ISO 9000 ("Quality management systems – Fundamentals and vocabulary") should, however, be the starting point for any organization wishing to understand the philosophy and principles on which the ISO 9000 series of standards is based. According to ISO 9000:2015, "*An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties. The quality of an organization's products and services is determined by the ability to satisfy customers, and their intended and unintended impact on relevant interested*

parties. The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer."

ISO 9000 goes on to describe the basic principles of quality and includes an extensive vocabulary that provide definitions for most of the common terms that are used in quality management. It is important to note that there is nothing in the definition of a quality management system that talks about "documents" or "procedures". The emphasis should be on managing processes in order to achieve planned results, rather than developing extensive documentation in a bureaucratic manner. Of course, some documents (in the form of procedures, work instructions, check-lists and so on) are likely to be needed in order to ensure that the processes are effectively managed, but the extent of that documentation and the associated records will depend on the particular **context** of the organization. Although not universally true, we might generally expect that small businesses with simple processes and products will need very little in terms of documentation in order to achieve their objectives, whilst large, complex organizations producing more sophisticated products, or providing critical services, will inevitably need more. We have to be careful, though, not to confuse this with "bureaucracy", which typically relates to **un-necessary** (non-value-adding) documentation.

The mentality we need to promote is that ISO 9000 requires the development of a quality management system that is **documented to the extent needed for it to achieve its objectives**, and it should not be regarded as a "system of documents".

ISO 9000 standards as a basis for sustainable development

Over the last 30 years, ISO 9001 has not only been extensively utilized to facilitate world trade but has also been used as a starting point for the development of other management system standards focusing (for example) on the environment, occupational health and safety, information security, anti-bribery and many others. These now form part of a consistent, harmonized portfolio of standards that use a common "high-level structure", terminology and some identical text to address common elements, as prescribed by Annex SL of the ISO Directives that all standards-writers are obliged to follow.

Back in 1979, when ISO/TC176 was first organized, global warming, climate change and biodiversity were not even on the radar screen, and it was only in 1987 (the year when ISO 9001 was born) that the landmark Brundtland Report "Our common future" was published. Formally known as the World Commission on Environment and Development (WCED), the Brundtland Commission's mission was to unite countries to pursue sustainable development together. Long before it became fashionable to be "sustainable", ISO had already begun preparing the ground by setting up Strategic Advisory Groups, organizing international conferences, and devoting its Strategic Plan to the theme of sustainable development. In the last two decades, ISO's portfolio of standards has not only increased to foster growth, support innovation and provide a solid base for economic sustainability, but also to broaden the scope of its work in the area of social and environmental performance, translating the global desire for a sustainable world into practical actions that achieve positive results. In other words, moving from a narrow focus on the quality of products and services to one that embraces a holistic "quality of life" perspective. Today, ISO's portfolio of approximately 26 000 standards provide business, government and society with solutions in all three dimensions of sustainable development – economic, environmental and societal.

The old "documented procedures demonstrated by records" approach was replaced in the year 2000 version of ISO 9001 by a more pragmatic "process approach" whereby organizations need to identify and understand the processes that are necessary to achieve the desired results and manage them (and their interactions) using the "Plan-Do-Check-Act" cycle at all levels, from the Board Room to the shop floor. Interwoven into the latest 2015 version of the standard is a focus on identifying the risks and opportunities associated with an organization's activities in order to mitigate the risks of generating non-conforming outputs and identify opportunities to "do things better". It is not the intention of ISO 9001:2015 to require organizations to adopt formal risk management methodologies, but rather to provoke a mentality of "risk-based thinking". Put simply, this means considering risk qualitatively (and, depending on the organization's context, quantitatively) when defining the rigour and degree of formality needed to plan and control individual activities and processes.

The TC 176/SC 2 strategic plan developed back in 2010 had reaffirmed ISO 9001's focus as providing confidence in the organization's ability to produce consistent, conforming products and services, with ISO 9004 aiming to provide confidence in the organization itself and its long-term sustained success. The new, recently published version of ISO 9004 will help

organizations improve their overall performance by releasing the full potential of their quality management system. That means balancing the needs and expectations of customers with those of other interested parties in a complex, demanding and ever-changing business environment. ISO 9004 now provides excellent linkage between the high-level Vision, Mission, Culture and Values of an organization, and how they can be realized via its policies, objectives and strategies deployed throughout all the organization's business processes. The Annex on self-assessment will also be useful for organizations wishing to make an analysis of the maturity of the various components of their QMS, with a view to focusing their improvement efforts.

INNOVATION AND CHANGE

As times change, so technologies improve, and this of course leads to new opportunities. The risks associated with these new technologies also need to be considered, however, and a balance achieved that is appropriate for the context of each individual business. Some organizations (particularly where human life might be at stake) are naturally "risk-averse", whilst others have a more voracious risk appetite and are willing to live with some uncertainty in order to pursue new business opportunities. ISO/IEC 31000 describes the principles and guidelines on which an effective risk management system should be based. The new ISO 50501 standard that is currently under development with also describe a structured approach to managing innovation. As an example, improvements in information technology, wireless communications, cloud computing, artificial intelligence and blockchain bring a whole range of technological opportunities that could only be dreamed of thirty years ago, but also imply new challenges in terms of information security, cyber-terrorism and business continuity in the event of service outages or other adverse events.

CONCLUSIONS

The ISO 9000 standards have come a long way in the last three decades, but still provide the bedrock onto which other sustainable development components can be constructed into a single, harmonized management system. From their origins in the manufacturing sector, with a series of prescriptive, "document-heavy" requirements, they are now more user-friendly to a whole range of organizations, with a focus on managing processes in order to achieve successful outcomes.

About the author

Nigel CROFT has been active in ISO/TC176 (the ISO Technical Committee responsible for the ISO 9000 series of standards) since 1995, currently serving as Chair of SC2, the subcommittee responsible for the ISO 9001 and ISO 9004 standards, and as a member of ISO's Joint Technical Coordination Group for management system standards. He also convenes the TC176 "ISO 9001 Brand Integrity" Task Group and is the official TC176 Liaison to the International Accreditation Forum.
Born in the UK, but currently with dual British and Brazilian citizenship, Dr Croft holds a first class honours degree in Natural Sciences from Cambridge University, and a Doctorate from Sheffield University. He is a Chartered Engineer and Chartered Quality Professional in the UK, a Fellow of the Chartered Quality Institute, an IRCA-registered Principal Auditor of Quality Management Systems and a Senior Member of the American Society for Quality.