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ISO 9000:

Three decades



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Special issue

ISO 9000 – Three Decades

Coordinating Editor: Prof. Ioan C. Bacivarov, PhD

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Coordinating Editor's Prologue

The ISO 9000 Family of International Standards – Three Decades

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*The international scientific journal **Asigurarea Calitatii – Quality Assurance** dedicates a special issue to a special anniversary in the field of standardization: three decades ago, in **1987**, the standard **ISO 9000** was published by the **International Organization for Standardization (ISO)**.*

*This standard was based on the **BS 5750** series of standards from the British Standards Institution (BSI), that were proposed to ISO in 1979. However, its history can be traced back some twenty years before that, to the publication of government procurement standards, such as the United States Department of Defense MIL-Q-9858 standard in 1959, and the UK's Def Stan 05-21 and 05-24 [6,7].*

*The **ISO 9000** family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.*

*The **ISO 9000 standards** are very dynamic and have undergone many revisions since their beginning, in order to make them more efficient and relevant.*

*The first revision was in **1994**, focused on trying to clear up the indistinct elements of the 1987 version as well as place a greater concentration on quality assurance through preventative actions. It also maintained its requirement for verification of compliance with documented practices.*

*One of the most significant and successful revisions is those from the year **2000**. The **ISO 9001:2000** version combined the previous ISO 9001, 9002, and 9003 versions into one and introduced a new set of eight core quality management principles that consist of: (1) Customer focus; (2) Leadership; (3) Involvement of people; (4) Process approach; (5) System approach to management; (6) Continual improvement; (7) Factual approach to decision making; (8) Mutually beneficial supplier relationships.*

The idea behind these principals is for them to act as a foundation that will help guide an organization towards improved performance and productivity.

*After the next revision, those from **2008**, the standard remained fairly consistent with the 2000 version and the eight core quality management principals. The main objective during this revision was to clarify the existing requirements and to design the document to work in congruence with ISO's other management standards, such as ISO 14001:2004.*

*It is important to mention that in 2009, **ISO 9004** (which accompanied ISO 9001:2000 for the first time) was revised to promote a sustainable business approach. This version focused on all stakeholders and not just customers and social conditions. [1,3,4,6,7]*

***ISO 9001** is undoubtedly the best known and most widely used of the many standards developed by the International Organization for Standardization (ISO).*

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In 2012, ISO TC 176 – responsible for ISO 9001 development – celebrated 25 years of implementing ISO 9001, and concluded that it is necessary to create a new QMS model for the next 25 years. This is why commenced the official work on big revision of ISO 9001, starting with the new QM principles. As a result of an intensive work of this technical committee, the revised standard ISO 9001:2015 was released in September 2015.

The most significant change to ISO 9001:2015 is that the entire document is now focused around the idea of risk-based thinking. An emphasis on leadership and increased flexibility regarding documentation are other notable changes in the 2015 revision.

We have dedicated a special issue to the launching of the standard ISO 9001:2015, moment that was considered by important specialists in the field as „beginning of a new era development of quality management systems”. [1,2]

The need for International Standards is very important as more organizations operate in the global economy. The family of standards ISO 9000 – together with the family of standards ISO 14000 – has become thoroughly integrated with the world economy.

During all these years, the **ISO 9000** family of international quality management standards and guidelines has earned a global reputation as a basis for establishing effective and efficient quality management systems.

According to the last ISO Survey of Certifications (2017), more than 1,644,000 valid certificates of ISO management system standards were reported worldwide (from which, more than 1,106,000 ISO 9001 certificates) [5]. This high number of certifications is another proof of the utility and of the success of these standards.

At the same time, a whole industry has arisen – during the last three decades – from the need for third-party audits to system management standards.

Genesis and Structure of the Special Issue

Beginning with the end of 2017, the Editor-in-Chief of the journal *Asigurarea Calitatii – Quality Assurance* and, at the same time, the coordinator of this special issue, Prof. **Ioan Bacivarov** contacted an important number of renowned specialists in the field in order to obtain their views and also the organizations they lead

concerning the family of standards **ISO 9000**, at their 30th anniversary.

The response to this approach has been very encouraging: consequently we are happy that we can include in this special issue the views of the leaders of the main international organizations involved in the development and implementation of ISO 9000 standards, including International Organization for Standardization (ISO/TC176) and International Certification Network – IQNet, as well as of the other top international experts in the field.

Achieving this special was done under time constraints related to the development, review and revision of articles* Completion of articles for this special issue involved an intense activity and a proper management: hundreds of messages were exchanged between the Coordinating Editor, potential authors and reviewers and all the problems were solved in a record time. Therefore we want to thank everyone who made this possible: authors, reviewers, and publishers.

Following are brief presentations by the Coordinating Editor about each article of this special issue, in their order of appearance.

The first two papers of this special issue present the points of view of top officials of organizations involved in the development / implementation of the ISO 9000 standards, namely **ISO (TC176/SC2)**, and **IQNet**.

In the opening paper to this special issue, Dr. **Nigel Croft**, the Chairman of ISO/TC176/SC2, the ISO sub-committee responsible for ISO 9001 and ISO 9004, analyses the evolution of the **ISO 9000 standards** during the last 30 years. A special attention is given to ISO 9001, the best-known standard of the ISO 9000 series and which is used extensively for third party certification in global supply chains for products and services.

Dr. Croft concludes that 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.

In the second paper of this special issue, the President of the International Certification Network – IQNet,

* Several articles were not framed in the time constraints related to publishing this special issue; consequently, they will be published in future issues of the journal *Asigurarea Calitatii – Quality Assurance*, but will be considered as part of this special issue.

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Mr. **Alexandru Stoichitoiu** underlines the fact that IQNet – one of the major users of ISO and ISO/CASCO documents – strongly supports ISO Strategy, supports ISO/CASCO activities and participates in various forms to these ones. The IQNet President analyses the results of an IQNet sponsored empirical research study on **ISO 9001:2015** transition process and certification benefits.

Organizations have to move from Product Quality to the next level of Quality of an organization by implementing an effective and efficient management system that is led by top management and is focused on the organization ability to meet the needs and expectations of its customers and other relevant interested parties, over the long term as the way to achieve sustained success of the organization. While ISO 9001:2015 focuses on providing confidence in the organization's products and services, the new standard **ISO 9004:2018** is focused on providing confidence in the ability of the organization to achieve sustained success. In his paper, Dr. **Isaac Sheps** – who is the convener of ISO TC176/SC2/WG25 responsible for the revision of the ISO 9004 standard – demonstrates the need for the above described development in quality and management systems.

The paper of **Dzedik, Ezrakhovich and Navolotskaya** addresses the steps in development of standardization and quality management and makes a prediction of the need for its further development using advanced information technologies, such as machine learning and artificial intelligence.

In his article entitled “ISO 9001: Three Decades of Leveraging Business Success in A Constantly Changing World” Mr. **David Balme** argues that **ISO 9001** return on investment over the last decades is most clearly tangible in life-critical industrial sectors. To explain how ISO 9001 achieved such a spectacular result, it is shown how the standard managed to regularly adjust its requirements to take up both local and global business challenges over time, sometimes in a disruptive way. It is also illustrated how relevant key quality management principles are to achieve corporate success. It is also reminded that not all components of our societies have yet benefited from ISO best management practices. Finally, a tentative outlook of new quality management principles is provided, based on process digitization and machine learning.

Smith, Kourouklis and Cano present the results of a research study which aimed to evaluate the impact the revised quality management standard ISO9001:2015 has had, through the introduction of the explicit risk-based thinking approach.

Their paper provides early additional knowledge relating to a risk-based thinking approach and the revised **ISO 9001:2015** quality management standard. It also points to the need for further review after the revised standard has become fully embedded and the 2008 equivalent has been made fully obsolete. Organizational value is also considered, for organisations looking to introduce an ISO based quality management system or modify existing quality management system to be capable of meeting the revised requirements.

Acknowledgments

This special issue has been made possible due to the contribution of numerous people involved in the domain of quality management and certification.

First of all, special thanks are due to the prestigious authors, who submitted valuable papers for this issue.

Last, but not least, we thank all the reviewers for taking time from their busy schedules in order to provide useful feedback on very short notice.

Our sincere thanks to all participants who made this special issue possible.

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About the author



Ioan C. BACIVAROV received the MSc in Electronics and Telecommunications (1971) as Major of Promotion (Valedictorian) in Telecommunications and the PhD in Reliability Engineering (1978). He is full Professor at the Electronic Technology and Reliability Department of Polytechnical University of Bucharest (UPB), Romania and Director of EUROQUALROM-ETTI laboratory, both beginning with 1996.

Dr. Ioan Bacivarov was an Invited Professor at ETH Zurich, Switzerland, TIMA-National Polytechnical Institute Grenoble and University of Angers, France and a Visiting Professor at several universities from European Union – including Erasmus University Rotterdam, ENSAM Paris, University of West Scotland, INP Grenoble, Polytechnic University of

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Professor Ioan Bacivarov is co-founder and President of the Romanian Association for Information Security Assurance – RAISA and coordinates the *International Journal of Information Security and Cybercrime – IJISC*. He is/was a member of the Board of SRAC and RENAR and is the President of NTC 144 ASRO-IEC (Dependability).

His teaching and research interests include quality and dependability (esp. reliability and security) engineering and management, electronic technology, and cyber-security. He has published 22 books, more than 250 papers and coordinated 50 national/international research & educational projects in the above areas.

Prof. Bacivarov is Scientific Chairman of the *International Conference in Quality and Dependability – CCF*, organized in Romania (from 1986) and member of the Scientific Board of several international conferences in quality and dependability including ESREL, MMR, QUALITA, PSAM a.o.

Dr. Bacivarov is currently Editor-in-Chief / Editor of several international scientific journals including: *Asigurarea Calitatii – Quality Assurance*, *Quality – Access to Success*, *Quality Engineering*, and *Forum Qualite Scientifique* and was an Editor of the journals *Optimum Q*, *Reliability Engineering & System Safety* and *Maintenance Management International* a.o. He coordinated 18 special issues in quality and dependability of the above mentioned journals, including „Quality efforts in Europe” – *Quality Engineering (USA)* – 1995 and the last two special issues of *Quality Assurance* concerning ISO 9000 series.

Reflections on 3 Decades of “ISO 9000”

Nigel H. CROFT

Chairman – ISO Subcommittee TC176/SC2 (Quality Systems)

Member – ISO Joint Technical Coordination Group

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

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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.

ISO 9001 - An Empirical Conclusion

Alexandru STOICHITOIU

IQNet President

Abstract

Established since 1990, IQNet is an international network of leading certification bodies. Currently the network consists of 34 partner certification bodies (IQNet partners) who share IQNet harmonized certification principles and methodologies. IQNet's main focus is on accredited Management system certification, for which ISO and ISO/CASCO standards provide the foundation. IQNet is based in Bern, Switzerland, from where the main common guidelines and joint initiatives are launched. In 2005, IQNet Ltd was founded as the certification division of the IQNet network. IQNet Ltd has its own accreditation and recognitions, with a principal focus on specialist and industry specific solutions, mainly in the field of social compliance and sustainability. IQNet Ltd delivers global certification services using the conformity assessment resources of its partner network. IQNet Ltd has chosen to perform its certification and assessment activities in strict accordance with the ISO/CASCO standards, notably ISO/IEC 17021-1 and other. As one of the major users of ISO and ISO/CASCO documents, IQNet is actively involved in the development and promotion of its work and documents. IQNet strongly supports ISO Strategy, supports ISO/CASCO activities and participates in various forms. In this paper, the IQNet President presents the results of an IQNet sponsored- empirical research study on ISO 9001:2015 transition process and certification benefits.

Keywords: IQNet, certification, ISO 9001:2015, transition process, research study

Organizational Quality – Guidance to achieve Sustained Success. The New ISO 9004:2018

Isaac SHEPS

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Abstract

The success factors of organizations are developing continuously and every few year's new success factors are added to the complex demanding and ever-changing competitive environment in which organizations operate. There is no doubt that the primary focus of an organization should be to achieve higher satisfaction of its customers by implementing rigorous processes to continuously improve its products and services quality - but in the current competitive environment this is not enough to achieve sustained success. Organizations have to move from Product Quality to the next level of Quality of an organization by implementing an effective and efficient management system that is led by top management and is focused on the organization ability to meet the needs and expectations of its customers and other relevant interested parties, over the long term as the way to achieve sustained success of the organization. While ISO 9001:2015 focuses on providing confidence in the organization's products and services, the new standard ISO 9004: 2018 is focused on providing confidence in the ability of the organization to achieve sustained success. In this paper Dr. Isaac Sheps who is the convener of ISO TC176/SC2/WG25 responsible for the revision of the ISO 9004 standard demonstrates the need for the above described development in quality and management systems.

Keywords: Quality, Management, Organization, ISO 9004, Quality of an organization, Sustained success

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Evolution of Quality Management – from the Book of the Dead to the Artificial Intelligence

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Abstract

The signs of origin of the quality management origination can be found at the very early stages of mankind development. However as a knowledge area the quality management started to form together with the global industrial revolution. The article addresses the steps in development of standardization and quality management and makes a prediction of the need for its further development using the most advanced information technologies, such as machine learning and artificial intelligence.

Keywords: quality management system, quality management, ISO 9001, machine learning, artificial intelligence

ISO 9001: Three Decades of Leveraging Business Success in A Constantly Changing World

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Abstract

ISO 9001 return on investment over the last decades is most clearly tangible in life-critical industrial sectors such as, e.g. aerospace, semiconductor, medical device and car manufacturing where defect rates have been downsized by several orders of magnitude. To partially explain how ISO 9001 achieved such a spectacular result, it is shown how the standard managed to regularly adjust its requirements to take up both local and global business challenges over time, sometimes in a disruptive way. It is also illustrated how relevant key quality management principles are to achieve corporate success. It is also reminded that not all components of our societies have yet benefited from ISO best management practices. Finally, a tentative outlook of new quality management principles is provided, based on process digitization and machine learning.

Keywords: ISO 9001, quality assurance, quality control, total quality management, TQM, product out, market in, overseas manufacturing, business success, failure, sustainability, breakthrough management, digital transformation, artificial intelligence, machine learn

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ISO 9001:2015 Introduction of Explicit Risk-Based Thinking - Benefit or Limitation?

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Abstract

This paper presents the results of a research study which aimed to evaluate the impact the revised quality management standard ISO9001: 2015 has had, through the introduction of the explicit risk-based thinking approach. Using semi structured interviews four key themes were identified; Impact, Benefits and Limitations, Training and Change Management. The results from this small scale introductory research study have provided an early insight into the impact the revised standard has had on both organisation and customer to date from a quality professional perspective. The results have shown that ISO9001:2015's introduction of explicit risk-based thinking will have a negligibly beneficial effect on the organisation and customer. The study has also identified that the introduction of the revised quality management standard has been considered as low impact /previously established either implicitly through the standards previous edition or as part of research participants pre-existing quality management systems and processes. This paper provides early additional knowledge relating to a risk-based thinking approach and the revised ISO9001:2015 quality management standard. It also points to the need for further review after the revised standard has become fully embedded and the 2008 equivalent has been made fully obsolete. Organisational value is also considered, for organisations looking to introduce an ISO based quality management system or modify existing quality management system to be capable of meeting the revised requirements.

Keywords: quality, quality management, ISO, ISO9001:2015, risk-based thinking, auditing, impact

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