

## ASIGURAREA CALITĂȚII – QUALITY ASSURANCE

Special Issue

ISO 9001:2015

Coordinating Editor: Prof. Ioan C. Bacivarov

### CONTENTS

- |   |    |
|---|----|
| <input type="checkbox"/> <b>The Standard ISO 9001:2015 – A Milestone in the Evolution of Quality Management</b><br><i>Ioan C. Bacivarov</i>   | 2  |
| <input type="checkbox"/> <b>Message of Dr. Nigel Croft, Chairman of ISO/TC176/SC2</b>   | 5  |
| <input type="checkbox"/> <b>Transitioning Accredited Certification to ISO 9001:2015</b><br><i>Randy A. Dougherty</i>  | 7  |
| <input type="checkbox"/> <b>ISO 9001:2015 Edition: A Fundamental Contribution to the Most Popular Standard of All Times Standardization and Conformity Assessment Perspective</b><br><i>Pedro Castro Alves</i>        | 9  |
| <input type="checkbox"/> <b>Coming Soon – New Era of ISO 9001:2015</b><br><i>Alexander Ezrakhovich, Pavel Nikanorov, Valentin Dzedik</i>  | 15 |
| <input type="checkbox"/> <b>Open to Change. How Expected Revisions to ISO 9001:2015 May Affect Sector-specific Standards</b><br><i>R. Dan Reid</i>  | 19 |
| <input type="checkbox"/> <b>ISO 9001:2015 : A Key Lever to Take Up the Challenges of Deregulated Markets, Change of Consumption Habits and Make the Best Use of Technological Breakthroughs</b><br><i>David Balme</i> | 23 |
| <input type="checkbox"/> <b>Risk and Risk Management in ISO 9001:2015</b><br><i>Titu-Marius I. Băjenescu</i>  | 26 |
| <input type="checkbox"/> <b>ISO 9001 – A Romanian Story</b><br><i>Dan G. Stoichițoiu</i>  | 30 |
| <input type="checkbox"/> <b>ISO 9001:2015 – An Example of Application in Serbia</b><br><i>Vidosav D. Majtorović, Miro Marković, Dragiša Kuzmanović, Jelena Mačužić, Valentina D. Marinković, Tatjana Šibalija</i>     | 32 |
| <input type="checkbox"/> <b>Changing the Rules – SRAC Vision for Transition to ISO 9001:2015 and ISO 14001:2015</b><br><i>Cristinel Roncea</i>  | 37 |

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## Coordinating Editor's Prologue

### The Standard ISO 9001:2015 – A Milestone in the Evolution of Quality Management

Ioan C. BACIVAROV\*

*EUROQUALROM, Faculty of Electronics, Telecommunications and Information Technology,  
University "Politehnica" of Bucharest, Romania*

*The international scientific journal **Asigurarea Calității – Quality Assurance** dedicates a special issue to a leading global event in the field of standardization: the launching of the new version of the standard **ISO 9001:2015**.*

*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 family of standards ISO 9000 – together with the family of standards ISO 14000 – has become thoroughly integrated with the world economy.*

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

*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.*

*This moment was considered by important specialists in the field as “beginning of a new era in the development of quality management systems”.*

#### GENESIS AND STRUCTURE OF THE SPECIAL ISSUE

*Beginning with April 2015, the Editor-in-Chief of the journal **Asigurarea Calității – 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 revision of ISO 9001.*

*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 9001:2015, including International Organization for Standardization (ISO/TC176), International Accreditation Forum – IAF and International Certification Network – IQNet, as well as of the other top experts in the field from Europe, America and Australia.*

*Achieving this special issue – whose appearance was scheduled for September 2015, simultaneously with the approval and publication of the revised standard ISO 9001:2015 – was done under severe constraints of time related to the development, review and revision of articles\*\* (including the summer period!). Completion of articles for this special issue involved an intense activity and a proper management: hundreds of messages were exchanged between the Editor, potential authors and reviewers and all*

\* Correspondence to Professor **Ioan Bacivarov**, PhD, Director of EUROQUALROM-ETTI-UPB, Editor-in-Chief of “*Asigurarea Calitatii – Quality Assurance*” and (former) Editor-for-Europe of “*Quality Engineering*” (U.S.A.), e-mail: [bacivaro@euroqual.pub.ro](mailto:bacivaro@euroqual.pub.ro), [ibacivarov@yahoo.com](mailto:ibacivarov@yahoo.com).

\*\* 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 Calității – Quality Assurance**, but will be considered as part of this special issue.

*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 three papers of this special issue present the points of view of top officials of organizations involved in the development / implementation of the revised standard ISO 9001:2015 «Quality management systems – Requirements», namely: the International Organization for Standardization – ISO (TC176/SC2), the International Accreditation Forum – IAF and the International Certification Network – IQNet.*

*In the opening message to this special issue, Dr. Nigel Croft, the Chairman of ISO/TC176/SC2, the ISO subcommittee responsible for ISO 9001 and ISO 9004 mentioned that – in his view – the revision of the standard ISO 9001 represents a milestone in the history of quality management and will update ISO's flagship standard to be more in line with modern business practices by a process of "significant evolution" rather than "revolution". Dr. Croft analyzed the most important improvements that were incorporated into ISO 9001:2015, too.*

*In the second paper of this special issue, the President of the International Accreditation Forum (IAF) Mr. Randy Dougherty emphasized the unprecedented collaboration between ISO and IAF for the revision of the standard ISO 9001. He mentioned the significant changes which enhances the business value of conforming to ISO 9001:2015, too. Finally, the key points for the transition to ISO 9001:2015 – in the vision of IAF – were outlined.*

*In his paper, entitled "ISO 9001:2015 Edition: A Fundamental Contribution to the Most Popular Standard of All Times", Mr. Pedro Castro Alves, the Managing Director of the International Certification Network – IQNet presented a standardization and conformity assessment perspective to this standard. The author mentioned that IQNet established a documented guidance on the certificate transition according to ISO 9001:2015.*

*The following articles of this special issue shows the vision on the revised standard ISO 9001:2015 of some well-known experts in the field from Australia, USA and Europe.*

*Mr. Alex Ezrakhovich, the Head of Australian Delegation at ISO/TC176, and collaborators presented in their paper the enormous efforts made by the ISO/TC 176/SC2 in order to implement the new version of the international standard ISO 9001:2015. The new terms introduced by ISO 9001:2015 were analyzed and the main changes from DIS to FDIS were provided.*

*The paper of Mr. R. Dan Reid – an American expert best known as an author of ISO TS/16949 and QS-9000 a.o. – analyzed how expected revisions to ISO 9001:2015 may affect sector-specific standards.*

*Though ISO 9001 has deeply penetrated very specific industrial sectors and shown multiple benefits in life critical businesses, large segments of our economy have not started yet implementing good quality management practices, mentioned Mr. David Balme in his paper. The author has highlighted the fact that it is expected that the new version of ISO 9001 will provide these tailing market players with clearer requirements to re-engineer their customer relationship and adapt smoothly to market changes initiated by deregulation, technological breakthrough and change in consumption habits.*

*One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to risk; a special attention was given to the analysis of the concepts of risk and of risk-based thinking, introduced in this standard. In this context, Mr. Titu Băjenescu presented the concepts of risk and risk management and analyzed how they are used in the revised standard ISO 9001:2015.*

*The following papers of this special issue present some national points of view regarding the standard ISO 9001.*

*Dr. Dan Stoichițoiu, the President of the Romanian Society for Quality Assurance (SRAC) and one of the veterans of quality in Romania, described the manner in which the standard ISO 9001 was implemented and evolved in the past three decades in Romania.*

*Prof. Vidosav Majstorović provided, together with collaborators, a detailed analysis of certification in the Western Balkans Countries and Serbia, based on various aspects, for seven standardized management systems, as well as an example of certification of a Serbian enterprise based on the revised ISO 9001 standard.*

*Finally, Dr. Cristinel Roncea specified, from the point of view of SRAC, the key areas of ISO 9001:2015 and ISO 14001:2015 where quality management systems and environmental management systems auditors will need to focus, and the actions to be established and applied.*

# ASIGURAREA CALITĂȚII – QUALITY ASSURANCE

Iulie – Septembrie 2015 Anul XXI Numărul 83

## 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.*

## NOTES

### Latest News

#### ISO9001:2015

Result of voting
<b>P -Members voting: 75 in favour out of 75 = 100 % (requirement &gt;= 66.66%)</b> <i>(P -Members having abstained are not counted in this vote.)</i>
<b>Member bodies voting: 0 negative votes out of 80 = 0 % (requirement &lt;= 25%)</b>
<b>Approved</b>

#### ISO9000:2015

Result of voting
<b>P -Members voting: 56 in favour out of 58 = 97 % (requirement &gt;= 66.66%)</b> <i>(P -Members having abstained are not counted in this vote.)</i>
<b>Member bodies voting: 2 negative votes out of 68 = 3 % (requirement &lt;= 25%)</b>
<b>Approved</b>

Standards will be published on the 23<sup>rd</sup> of September 2015



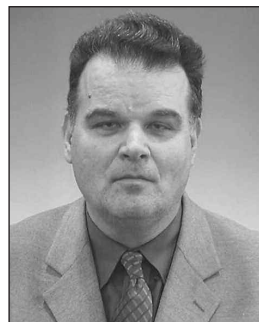
[1] In mid September 2015, when this special issue was ready for print, a news release in standardization field (<http://www.insidestandards.com/iso-9001-2015-approved/>) mentioned that:

*The ISO 9001:2015 ballot has been approved. According to ASQ, who released the ballot results, there were 75 approvals, zero disapprovals, and 5 abstentions (Canada, Honduras, Kazakhstan, Luxembourg, and Qatar). (...) The release of ISO 9001:2015 is the culmination of a long review process.(...) The final International Standard version of ISO 9001:2015 is scheduled for release on September 23.*

By adopting ISO 9001: 2015, a new stage in the evolution of quality management systems began.

[2] This image regarding the vote for the ISO 9000 standards was sent, when the journal was ready for print too, by Mr. **Alex Ezrakhovich**, the Head of Australian Delegation at ISO/TC176, We included it because it is a interesting document for the recent history of quality. (**I.C. Bacivarov**)

## About the author



**IOAN C. BACIVAROV** received the MSc in Electronics and Telecommunications (1971) and the PhD in Reliability Engineering (1978). He is a full Professor at the Electronic Technology and Reliability Division 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, TIMA – National Polytechnical Institute Grenoble and University of Angers and a Visiting Professor at several universities from European Union – including Erasmus University Rotterdam, ENSAM Paris, University of West Scotland, INP Grenoble, Polytechnical University of Catalunya a.o. (beginning with 1992).

Prof. 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 45 research projects in the above areas.

He is Scientific Chairman of the *International Conference in Quality and Dependability –CCF*, organized in Romania (from 1992) 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 Calității – Quality Assurance*, *Calitatea – Acces la succes*, *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.

Prof. Bacivarov contributed to the development of higher education in technical universities from Romania in the field of quality and dependability in his capacity of international coordinator of the EU educational project TEMPUS JEP 11300-96 “EUROQUALROM” and as a coordinator of the postgraduate program of UPB in the field.

## Message of Dr. Nigel CROFT, Chairman of ISO/TC176/SC2



*As Chair of ISO/TC176/SC2, the ISO subcommittee responsible for ISO 9001 and ISO 9004 (among other standards), I am very excited about this latest revision to ISO 9001 (“Quality Management Systems – Requirements”). In my view it represents a milestone in the history of quality ma-*

*made), it’s incredible to realize that in those days, many organizations were controlling documentation by “rubber-stamping” hard copies of procedures; there was no “Google”, no “Cloud”, no “wireless internet” or Smartphones, and only limited software for statistical, analytical and other applications.*

*In my view, some of the most important improvements that are being incorporated into ISO 9001:2015 are as follows:*

- ❑ *ISO 9001:2015 will use the new harmonized High Level Structure that has been developed by ISO’s Joint Technical Coordination Group, and published in Annex SL of the ISO Directives. This will make life easier for organizations that choose to have a single (“integrated”) management system to meet the requirements of multiple standards such as ISO 9001 (Quality), ISO 14001 (Environmental), ISO 27001 (Information Security) and the future ISO 45001 for Health and Safety Management Systems (which is expected to replace OHSAS 18001), among others.*
- ❑ *The new version of ISO 9001 places much more emphasis on the service sector, by making the overall language of the standard more user-friendly for service organizations, and adapting some of the traditional clauses to focus more on the needs of the service sector. Not only have we given more attention to requirements related to **service** design and development, and “measuring equipment” as*

# ASIGURAREA CALITĂȚII – QUALITY ASSURANCE

Iulie – Septembrie 2015 Anul XXI Numărul 83

*it relates to the service sector, but the standard will now specifically use the terminology “products and services” instead of just “products”, as before.*

- ❑ *We are maintaining a strong emphasis on the “Process Approach” that has been so successful in the 2000 and 2008 versions of the standard, whereby an organization needs to manage its processes in order to achieve the desired outcomes (which, in the case of ISO 9001, means providing customers with “consistent, conforming products”).*
- ❑ *Interwoven into the new standard is a focus on “risk-based thinking”, whereby an organization needs to identify the risks (and opportunities!) associated with its activities, and take actions to mitigate the risks of generating non-conforming products (including, of course, services). All processes needed for the quality management system have to be managed using the Plan-Do-Check-Act cycle, but some need a higher degree of control than others if they are to contribute to the organization’s ability to meet its objectives. It is not the intention of ISO 9001:2015 to require all 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 when planning and controlling individual activities and processes.*
- ❑ *ISO 9001:2015 also places much more emphasis on the ability of a quality management system to “deliver on its promise”. The absolute measure of the effectiveness of the system is not the number of documented procedures, the hours dedicated to training, or the number of pieces of calibrated measuring equipment – it is the organization’s ability to provide confidence in its ability to consistently provide products and services that meet the requirements of customers and other relevant interested parties (such as regulators, for example). Throughout the new version of ISO 9001, from the strategic to the operational level, this philosophy that “Output Matters!” has been emphasized.*

*There will of course be other changes, and it is to be hoped that once the users of ISO 9001 have had a chance to read and digest them, they will recognize the benefits that they will be able to achieve by implementing the 2015 version of the standard.*

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## About the author



Dr. **NIGEL CROFT** has been involved 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. He has represented TC 176 at ISO’s Conformity Assessment Committee (“ISO/CASCO”), where he served on the Chairman’s Policy Committee, and as a member of the strategic-level ISO/ILAC/IAF Joint Working Group which provides oversight of global management systems certification.

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, England, and a Doctorate in Materials Science from Sheffield University. He is a Chartered Engineer and Chartered Quality Professional in the UK, a Fellow of the Chartered Quality Institute and a Senior Member of the American Society for Quality.

# Transitioning Accredited Certification to ISO 9001:2015

**Randy A. DOUGHERTY**

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## **Abstract**

The President of the International Accreditation Forum (IAF) emphasizes the unprecedented collaboration between ISO and IAF for the revision of the standard ISO 9001. He mentioned the significant changes which enhances the business value of conforming to ISO 9001:2015, too. Finally, the key points for the transition to ISO9001:2015 - in the vision of IAF - are outlined.

**Keywords:** Standard, ISO, ISO 9001:2015, ISO/FDIS 9001, International Accreditation Forum, IAF, Quality Management System, Certification, Transition

# ISO 9001:2015 Edition: A Fundamental Contribution to the Most Popular Standard of All Times Standardization and Conformity Assessment Perspective

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## **Abstract**

Quality is intrinsic to mankind, especially if related to quality of life and survival issues. Although the concept of “quality” evolved with time, only during the 20th century did it acquire a systematic perspective and was developed through successive scope broadening stages. The dissemination and adoption of quality management system criteria, procedures and tools were largely promoted by standardization (e.g. through ISO 9000 series) and conformity assessment activities, like third party certification, supporting benefits for organizations worldwide. The scope of management system standardization activities was comprehensively enlarged during the last few years, and now includes most of organizational management areas not just with horizontal and global application, but also according to the specifics of a diverse set of economic sectors. This said, a complex and challenging scenario was set up for the ISO 9001 revision process under ISO Technical Committee 176/ but with contribution from different stakeholders through a systematic and participated process. Supported by a clear base-line and defined goals, standard writers incorporated a new structure and some other key changes, and the revised international standard publication is considered to meet with the initial expectations. Some of the new features of the revised normative reference are supported by ISO’s High Level Structure applicable, since 2011, to all management system standards, but other resulted from the incorporation of predominant interpretations, the inclusion of innovative management tools and the consideration of stakeholders needs. By now, and around the globe, millions of professionals are getting familiar with the new ISO 9001:2015 requirements (e.g. like risk management or context analysis) and are preparing implementation programmes or certification transition plans. The past, present and future efforts of all interested parties will definitely produce an effective contribution to the sustainability of ISO 9001 as the prominent quality management standard and as the most used, most commented and most appreciated normative reference in the world.

**Keywords:** Quality, Standardization, Conformity assessment, Certification, ISO, Management System, ISO 9001, Revision process, ISO 9001:2015, Changes, Implementation, Transition

## **References:**

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- [2] Implementation Guidance for ISO 9001:2015, ISO /TC 176/SC2 / N1277, 2015
- [3] Transition planning Guidance for ISO 9001:2015, IAF ID9, 2015
- [4] The ISO survey of management system standard certifications, 2013



[5] ISO 9001 and ISO 14001 2015 edition transition guidelines, P305\_OD001\_15, IQNet

# Coming Soon - New Era of ISO 9001:2015

**Alexander EZRAKHOVICH<sup>1</sup>, Pavel NIKANOROV<sup>2</sup>, Valentin  
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<sup>1</sup> Consulting Company "AEConformity Pty Ltd", Sydney, Australia; <sup>2</sup> Certification Association  
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## **Abstract**

This article is devoted to the development of the new version of the International Standard ISO 9001:2015«Quality management systems - Requirements». The enormous efforts made by the ISO/TC 176/SC2 into this aim are mentioned. The new terms introduced by ISO 9001:2015 are analyzed and the main changes from DIS to FDIS are provided. This article also outlines the approved by the International Accreditation Forum (IAF) Transition Planning Guidance for ISO 9001:2015.

**Keywords:** International Organization for Standardization, ISO, ISO/TC 176/SC2, ISO 9001:2015, revision of ISO 9001, quality management system, organizational environment, processes interaction, risk-based thinking, knowledge organization

## **References:**

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- [3] IAF ID 9: 2015 Transition Planning Guidance for ISO 9001:2015 (Issue 1, issued on 12 January 2015; Application from 12 January 2015)

# Open to Change. How Expected Revisions to ISO 9001:2015 May Affect Sector-specific Standards

**R. Dan REID**

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## Abstract

Sector-specific standards often include language from ISO 9001 to address quality management systems requirements. Changes expected to ISO 9001:2015 - including those related to new definitions and requirements - will certainly affect how individual sectors, such as automotive, aerospace and medical devices, handle upcoming revisions to their own guidance documents.

**Keywords:** Quality, ISO, Standard, Sector-specific standard, ISO 9001:2015, QMS DIS, Management system, Automotive, Aerospace, Revision, Changes

*Asigurarea Calitatii - Quality Assurance Editor's Note: This paper was reprinted with permission from Quality Progress © 2015 ASQ, [www.asq.org](http://www.asq.org). Special thanks to Mrs. Lynelle Korte, Mr. Brian LeHouillier, and Mrs. Gretchen Peterson from the American Society for Quality (ASQ) for granting this permission. (I.C. Bacivarov)*

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- [2] R. Dan Reid, "Into the Future," Quality Progress, March 2014, pp. 55-57
- [3] Nigel H. Croft, "ISO 9001:2015 and Beyond - Preparing for the Next 25 Years of Quality Management Standards," International Organization for Standardization, <http://bitly.com/next25years>, Aug. 28, 2012.
- [4] International Organization for Standardization and International Electrotechnical Committee, ISO/IEC Directives Part 2 - Rules for the Structure and Drafting of International Standards, edition 6, April 2011, clause D.4.8, p. 59, <http://bit.ly/structure-and-drafting>.
- [5] Is defined as a "role to be carried out by a designated unit of the organization" in ISO 9001:2015 Draft International Standard - Quality management systems - Requirements.
- [6] Croft, "ISO 9001:2015 and Beyond-Preparing for the Next 25 Years of Quality Management Standards," see reference 3.
- [7] International Organization for Standardization, ISO 9001:2008, Quality management systems - Clause 8.1 Planning, Measurement and Analysis.
- [8] Wikipedia, Seven Basic Tools of Quality, <http://bit.ly/seven-basic-tools>, May 4, 2015.
- [9] International Organization for Standardization, ISO 9001:2015 Draft International Standard - Quality management systems - Clause 6.1 Actions to Address Risks and Opportunities.
- [10] International Organization for Standardization, ISO 9001:2015 Draft International Standard - Quality management systems - Clause 0.5 Risk-based thinking.

# ISO 9001:2015: A Key Lever to Take Up the Challenges of Deregulated Markets, Change of Consumption Habits and Make the Best Use of Technological Breakthroughs

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## **Abstract**

Though ISO 9001 has deeply penetrated very specific industrial sectors and shown multiple benefits in life critical businesses, large segments of our economy have not started yet implementing good quality management practices. It is expected that the new version of ISO 9001 will provide these tailing market players with clearer requirements to re-engineer their customer relationship and adapt smoothly to market changes initiated by deregulation, technological breakthrough and change in consumption habits.

**Keywords:** quality management, risk, stakeholders, market change, ISO 9001, life critical, aerospace, medical device, automobile industry, real estate, media, bank, telecommunication operator, railway company

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- [3] [https://fr.wikipedia.org/wiki/Free\\_\(entreprise\)](https://fr.wikipedia.org/wiki/Free_(entreprise)).
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# Risk and Risk Management in ISO 9001:2015

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## Abstract

The objective of risk management is to reduce different risks related to a pre-selected area, up to an acceptable level. He may refer to numerous types of threats caused by environment, technology, humans, organizations and politics. Starting or developing a project always requires taking risks. That is why it is important to identify, analyse, control and manage these risks.

**Keywords:** Risk, risk management and opportunities in ISO 9001:2015, prevention, planning, analyzing, avoidance and minimization of risk management

## References:

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# ISO 9001 - A Romanian Story

**Dan G. STOICHIȚOIU**

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## **Abstract**

The paper work presents - in the vision of the President of the Romanian Society for Quality Assurance (SRAC), one of the veterans of quality in Romania - the manner in which ISO 9001 standard was implemented and evolved in the past three decades in Romania.

**Keywords:** Quality, Quality Management, ISO 9001, ISO CASCO, Romanian Society for Quality Assurance, SRAC, SRAC CERT

# ISO 9001:2015 - An Example of Application in Serbia

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## Abstract

ISO 9001 has been considered as the "engine" of development of business standardization process since, its first model issuing, in 1987. Nowadays, in the second decade of the 21st century it is experiencing fast development, again mainly thanks to the new edition of the model - ISO 9001:2015, which is expected to contribute to even more worldwide use of integrated management systems. Regarding data from 31st December 2013, there was in the world: (i) 1,564,884 certificates of ISO 9001, 13485, 14001, 16949, 22000, 27001 and 50001, of which the number of ISO 9001 was 1,129,446, and of ISO 14001 - 301,647 certificates. It is estimated that the total number of certificates, including all standardized management systems (SMS), will reach over 1.6 million by 31 December 2014, of which 1,150,000 would be for quality management systems (QMS). The new QMS model represents the new framework, which is expected to give a strong impetus to the development and implementation of business standardization. This paper provides a detailed analysis of certification in the Western Balkans Countries and Serbia, based on various aspects, for seven standardized management systems for 2013, as well as the first example of the certificate of the new QMS in Serbia.

**Keywords:** Business standardization, ISO, QMS, Analyses, Serbia, ISO 9001:2015, New model

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# Changing the Rules - SRAC Vision for Transition to ISO 9001:2015 and ISO 14001:2015

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## **Abstract**

This paper specifies, from SRAC viewpoint, the key areas of ISO 9001:2015 and ISO 14001:2015 where quality management systems and environmental management systems auditors will need to focus, and the actions established and applied by SRAC to maintain its position as a leader in management system certification, in the context of the transition to these two new standards.

**Keywords:** Audit, Improvement, Business, Management systems, SRAC, ISO 9001:2015, ISO 14001:2015

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