

## THE CHALLENGES OF TRANSITION TO THE NEW ISSUE OF ISO 9001

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### ABSTRACT

*The 2015 release of the ISO 9001 international quality management standard introduced a series of changes that are affecting processes and people altogether and ultimately the organisations as a whole. As transition deadline is in sight, organisations ought to be working their way through the new requirements, especially the major ones such as: risk-based approach introduction, changes of requirements related to responsibilities and changes regarding the documentation requirements. ISO 9001 is one of the most used quality management standard in Romania with more than 12,000 valid certificates recorded for 2016 hence any change affecting the standard also affects a large number of the registered companies in Romania. In that respect and as a continuation of previous work, the objective of present research is to identify the gaps between what managers know and what they do about these changes. Our aim is to explore whether organisations and their managers are ready at least to cope with the major changes, if they understand the impact of those changes when cascading through organisation as management and manager's approach to change is overwhelmingly important for any organisation.*

**KEYWORDS:** *management, risk, quality management, leadership, organisational objectives.*

**JEL CLASSIFICATION:** *M10, L20*

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### 1. INTRODUCTION

Business is about taking risks. It is about how managers manage the risk and what makes the difference. Some deal with it and some just fall back on an ad hoc/do nothing approach. These days, however, businesses are forced to find their way through rough waters with sudden changes of rules and uncertainty of outcomes. The influence of the paradigm shift from control-oriented risk management, to managed risk is more and more visible on various aspects and levels of organizational management, especially when it comes to small and medium enterprises. Managers are nowadays exposed to a wealth of changes of major concepts: quality, risks, opportunities all having direct impact on company's profitability and success.

"Risk is inherent in all aspects of a quality management system. 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". (ISO, n.d.)

„ISO 9001 is one of the world's most widely used quality management system standards, with over one million organizations certified to it in over 170 countries around the world" (Naden, 2016). This can help organizations improve the quality of their work and the products and services they

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provide, thus improving the trust of their customers and other stakeholders and especially the overall performance of businesses. (ISO, 2016)

The 2015 version of ISO 9001 documents few major differences from the 2008 version:

- Management representative is no longer formally required anymore; leadership does and it is expected that the whole management team would be involved and committed toward quality;
- Introduction of risk-based approach. The concept was implicit through the 2008 version of ISO 9001 as a preventive action required to be considered as part of the process approach; the new version makes it explicit;
- Documentation requirements are minimized. The 2015 version asks mostly for records as opposed to the previous version that was asking explicitly for procedures.

Starting from these differences, our research aims to identify how, and if, the management teams of some Romanian SME's can cope with all these changes, if they understand their meaning and how is it that they plan to adapt to these changes.

## 2. LITERATURE REVIEW

The constant change of both humans and organisations is acknowledged and perceived as an inevitable part of reality; however, most of the times, one can observe an obvious resistance to change (Verboncu & Irimie, 2016).

Pirsig (1974, p.185) embodies quality in a metaphor: „The quality is neither a mind nor a matter, but a third entity independent of the two... Even though Quality can't be defined". Kelemen (2003, p.14), starting from Pirsig's statement, develops the idea that: „Quality is considered as something beyond definition, a direct experience that can be understood only after one has been exposed to a set of objects that display its characteristics. Thus, quality is an embodied phenomenon and therefore can't be approached simply through cognition. Indeed, quality triggers in individuals not only a rational response but also emotions and sensations such as pleasure, pain, hate, and happiness.”

To answer the raising organisations' demands, Raja Sreedharan, Raju & Srivatsa Srinivas (2015) consider that will occur an evolution of quality „drastically. As a result, various quality management procedures have been implemented in varied kinds of organisations. A review of the quality principles such as Total Quality Management, Lean, Six Sigma and Lean Six Sigma is discussed in order to provide an understanding for implementing quality principles in different organisations, which includes manufacturing, service, healthcare, government, non-profit organisations, transportation and logistics, process industry, etc.”

Some specialists consider that „with the introduction of quality techniques, the effectiveness of organisations has improved. And these techniques are generic in nature and can improve the efficiency of any organisation. But, the implementation policies in different organisations vary with the type of organisation.” Raja Sreedharan, Raju & Srivatsa Srinivas (2015, p.351) while Savic et al. (2016) state that „certification in the studied economy is being performed pro-forma”.

People are the active, dynamic component involved in the quality management systems as expressed by the quality management principles (customer orientation, leadership, continual improvement etc.) according to the requirements of ISO 9001 (Bakotić & Rogošić, 2015; Zeininger, Irimie & Mihai, 2016). „Implementation of employee involvement (as one of the infrastructure Quality Management practices) might be crucial for the implementation of process approach, system approach to management, continual improvement and factual approach to decision-making (core Quality Management practices).” (Bakotić & Rogošić, 2015, p.1209) Employee involvement could be achieved by applying various methods such as: employee training, communication, empowerment and rewards and recognition and has a positive impact over implementing a quality management systems and its continuous improvement.

The new risk based approach of quality management systems according to ISO 9001:2015 requires dedicated employees, "risk professionals" (Irimie, Zeininger & Mihai, 2016) with a changed mentality, so that they could develop a risk culture within the organisations, hence, ensuring development and implementation of a framework to perform and report on risk measurements (Institute of Risk Management, 2016).

Total Quality Management philosophy emerged, as a result of companies' strive for success, during the battle for competitiveness. TQM philosophy is, as Ahire, Landeros & Golhar mentioned in 1995 „a revolutionary approach to effective management". Harris (1995) is also presenting it as a „quality initiative" through which western companies answers the high competition pressure.

Lack of a solid theoretical framework to classify the work done causes sometimes confusions even for specialists, like, for example, when discussing about „the three types of improvements: continual improvement, quality improvement and process improvement". Matthews & Marzec (2015) explore the fine lines between the three areas and based on a systematic review of literature explained the three terms individually and in combination, suggesting a new model and new research directions.

There are also many more studies on the impact of implementing a quality management system and implementing risk management in an SME (Dubey & Kumar, 2017; Verbano & Venturini, 2013; Zeininger & Irimie, 2015), however none yet looking at the challenges that the Romanian SME's managers need to overcome when making the transition to the new issue of ISO 9001. To understand how and if they are prepared to face these challenges we have dedicated a part of our research to investigate this issue.

### **3. THE SCOPE OF THE RESEARCH**

The research presented in our paper is part of a larger research on the impact of using a Quality Management System over organisations.

Out of the 80 companies questioned, some 73 replied to our questionnaire, but with 7 answers not complete, the data collected from only 65 were used in this paper.

All the companies are Romanian based SME's managed either by the owners wither by managers, all Romanians for as much as about 95% of the respondents. A brief sample company profile has the following main features: Romanian based company, approximately 80% are managed by the owner, around 25-30 employees and with a quality management system implemented for about 3 years.

The aim of our research is to understand how all the changes of the recent issue of ISO 9001 were received by managers, whether they understand their meaning and how they strive to adapt to them.

### **4. RESEARCH METHODOLOGY**

Data were collected by applying a questionnaire developed by the authors. The questionnaire has 10 questions with only 3 options to answer: yes, no, I don't know. The questionnaire is the one in Table 1.

In some 10% of the cases, an interview was also conducted with the respondents in order to further understand their answers. Where significant, their remarks were quoted in this paper. No qualitative processing was involved, only quantitative.

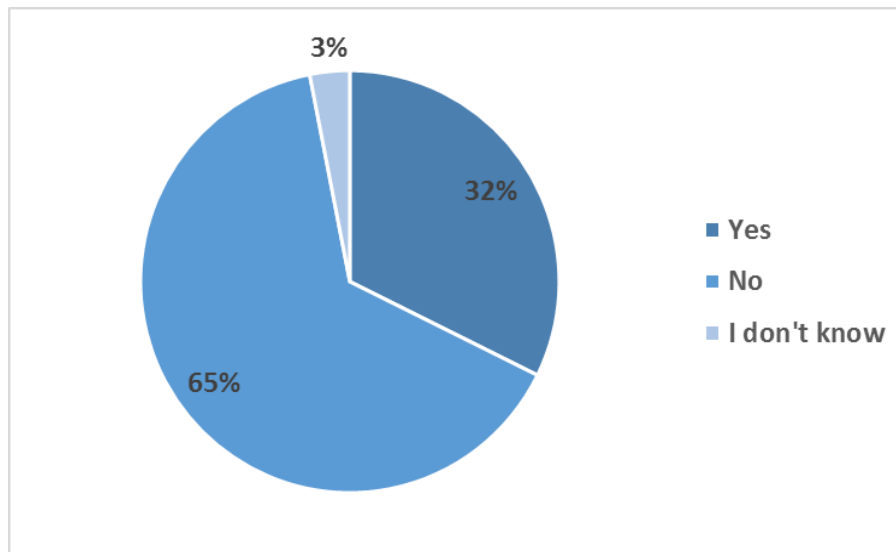
**Table 1. Questionnaire**

	<b>Item</b>	<b>Answers' options</b>
1.	In your opinion, not having anymore a management representative formally appointed would make the QMS work better?	Yes; No; I don't know
2.	In your opinion, taking responsibility for the QMS as a management team, would ensure better control over the system?	Yes; No; I don't know
3.	In your opinion, risk-based approach, would enhance the efficiency and effectiveness of the managerial process?	Yes; No; I don't know
4.	In your opinion introducing risk-based management approach would be beneficial for your organisation?	Yes; No; I don't know
5.	In your opinion, introducing the risk-based concept would favour the proactive attitude of management toward risks associated with organisational objectives?	Yes; No; I don't know
6.	Would you agree that introducing the risk-based concept through ISO 9001 reduced the number of prescriptive requirements and favoured the performance-oriented ones?	Yes; No; I don't know
7.	Introducing the risk-based concept would make a Quality Management System easier to implement, maintain and improve?	Yes; No; I don't know
8.	In your organisation, is risk management part of the general management?	Yes; No; I don't know
9.	In your opinion, would resource allocation to treat risks, generate the risk of not having enough resources for your main processes?	Yes; No; I don't know
10.	In your opinion, would the risk-based concept generate the need to re-dimension the processes?	Yes; No; I don't know

*Source:* authors

## 5. FINDINGS AND CRITICAL ANALYSIS

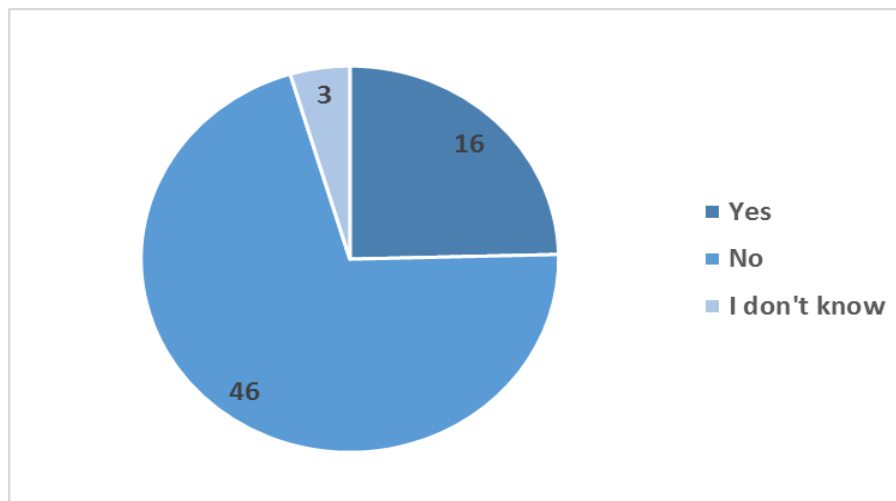
The first question, asked for respondents opinion on the use of a "management representative", as a member of the managerial team designated to coordinate and manage the quality management system. It was a highly visible position that is now not specifically required anymore, by the new issue of the standard. The answers are presented in Figure 1, below:



**Figure 1. Answers to Question 1.**  
*Source: authors*

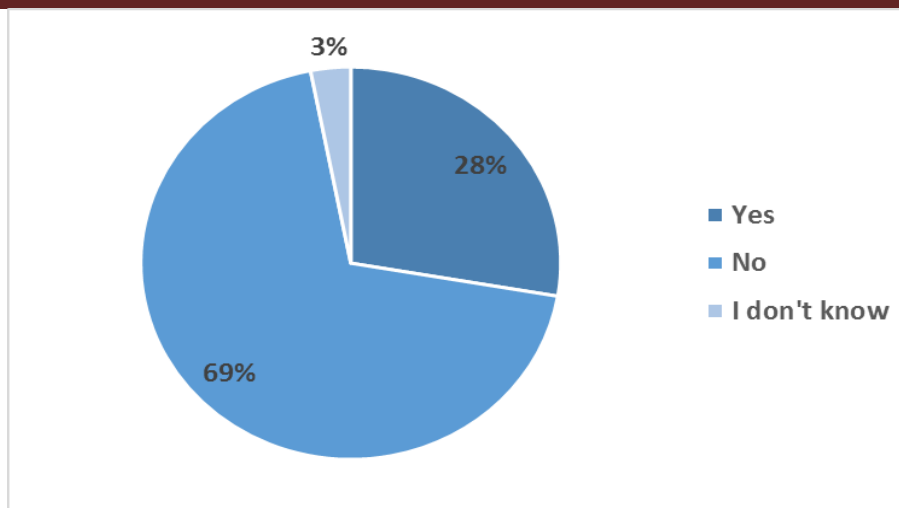
Two thirds of the respondents are afraid that not having a designated management representative would affect, in a negative manner, the Quality Management System. They are concerned that diffuse responsibility will result in lack of ownership.

Next question was about getting even further into the "management representative" matter, by enquiring whether taking responsibility as a team as opposed to a person, would possibly make a (positive) difference. The opinions of our respondents are presented in Figure 2.



**Figure 2. Answers to Question 2.**  
*Source: authors*

By looking at the results it is even clearer that diffuse management is a high concern among our respondents – they see it as a threat to QMS. As managers, it appears they know that collective responsibility means no responsibility, hence, if the team is responsible, is to be expected that each member of the team will act based on the assumption that itself has no responsibility on doing what is expected because others, someone, will just do it. As one of the responders commented: "It will be like before'89: everything is ours (i.e. the people) so nobody owns 'it, therefore nobody is accountable!"

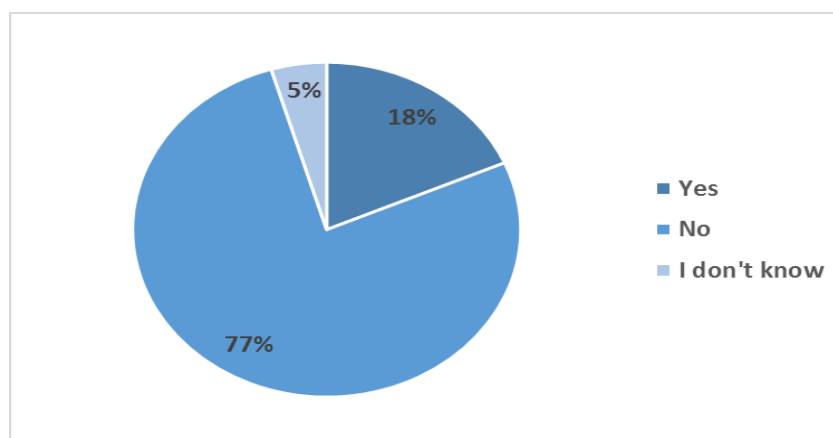


**Figure 3. Answers to Question 3.**

*Source:* authors

One of the major changes introduced by the new issue of ISO 9001, the risk-based approach, is subject of the third question: „In your opinion, risk-based approach in QMS would enhance the efficiency and effectiveness of the managerial process?” The answers are presented in Figure 3 and showcase mostly the degree of knowledge on the subject, i.e. the risk-based approach, as well as the degree of confidence in the concept itself with regard to its applicability. In other words, managers simply don't connect the dots – objectives and the associated risk. In their view, managing to reach objectives and managing risk are two separate, unrelated activities.

Question 4 asks for respondent's opinion on whether „introducing risk-based management approach would be beneficial for your organisation?” and shows the same degree of non-confidence in the new concept, as the previous answers, on the yet unknown benefits of the changes. Figure 4 shows that a large majority of the respondents, 77%, are convinced that risk-based approach is not beneficial for the organisation.

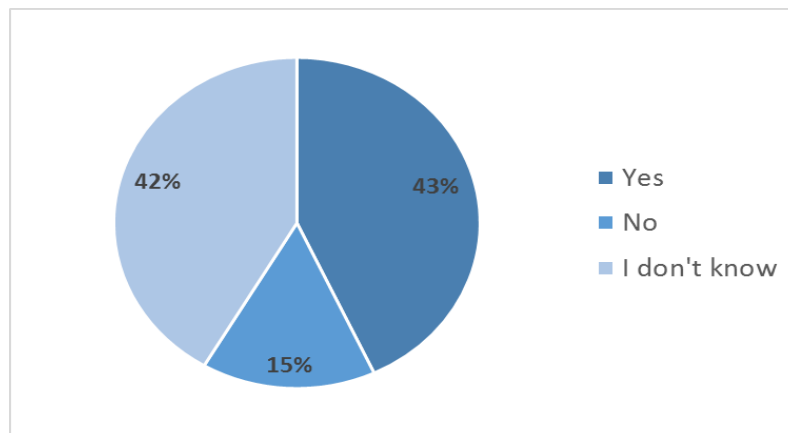


**Figure 4. Answers to Question 4.**

*Source:* authors

Question 5 probes the depths of the cleavage perceived, by managers, as existing between risk management and general management – as depicted in previous three questions (43% I don't know). Many respondents, during the interviews, asked „what is the point to this proactive approach?” In other words, changing the attitude or the approach toward risk makes not much

difference to improve their current performance as managers. Or so they still think of it. The distribution of answers is depicted in Figure 5.

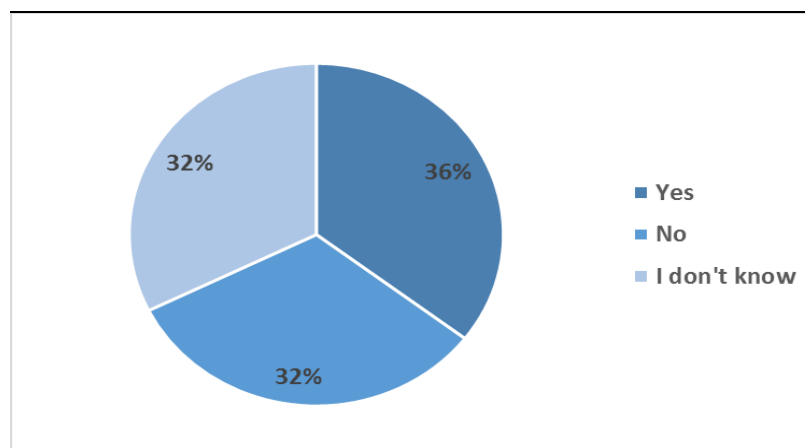


**Figure 5. Answers to Question 5.**

*Source: authors*

Question 6 is a more specific question addressing one of the most common uses of the new paradigm (risk based thinking in management) in ISO 9001:2015 compliant quality management systems. The question asked if the newly introduced concept shifted the perception over the standard from a simple prescriptive set of rule to a more performance management oriented guideline. Not surprisingly, the almost perfect balanced distribution of answers shows a yet very poor understanding of this referential (Figure 6).

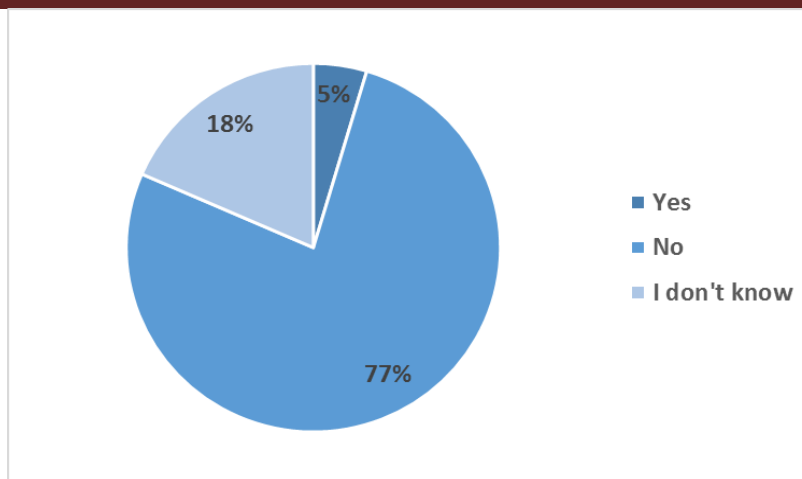
Managers do not grasp the reason why management standards, in their entirety (such as ISO 9001, ISO 14001, and ISO/IEC 27001 etc.) moved towards adopting risk based thinking as a major paradigm shift in their approach to management. That shows a worrying obliviousness to the fact that those standards simply responded to a greater change: the shift of the economic paradigm towards agility in front of unpredictability in a world where grave dangers lurk.



**Figure 6. Answers to Question 6.**

*Source: authors*

In conjunction with question 6, the next question, number 7, shows that the key of understanding the results is: less requirements, hence simpler and easier.

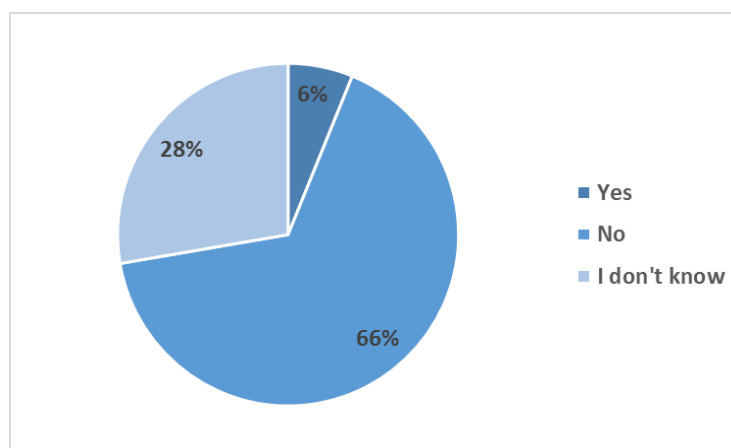


**Figure 7. Answers to Question 7.**

*Source: authors*

The authors could observe in practice, that a common barrier to the process of transition or implementation of the new management standards – in particular the quality management system ISO 9001:2015 compliant is the lack of understanding of what the standard actually requires. The requirements of previous issues were clear for everyone: where the standard used “shall” it meant a documented requirement was needed. Shifting from “documented procedures” to “documented information” and doing that by using „risk based thinking” prove to be beyond most managers abilities to understand and grasp (Figure 7).

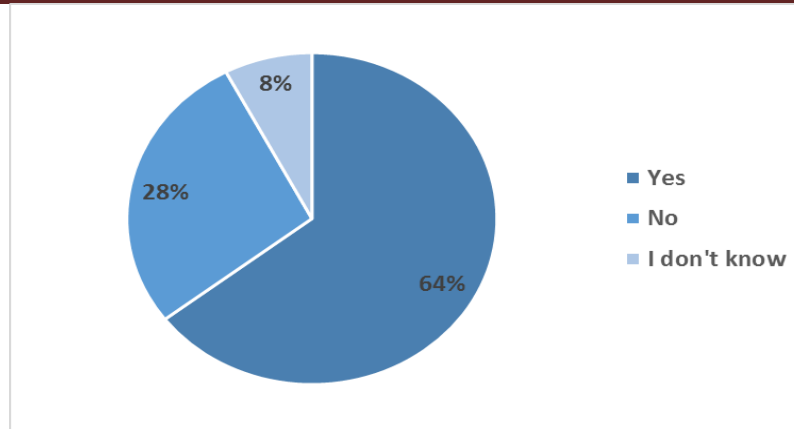
Question 8 – the distribution of the answers to this question only comes to openly state what managers seem to think that „risk management is not our job”. As one of the responders put ‘it: „this is for someone like an insurance agent or something ....” Distribution of responses is presented in Figure 8.



**Figure 8. Answers to Question 8.**

*Source: authors*

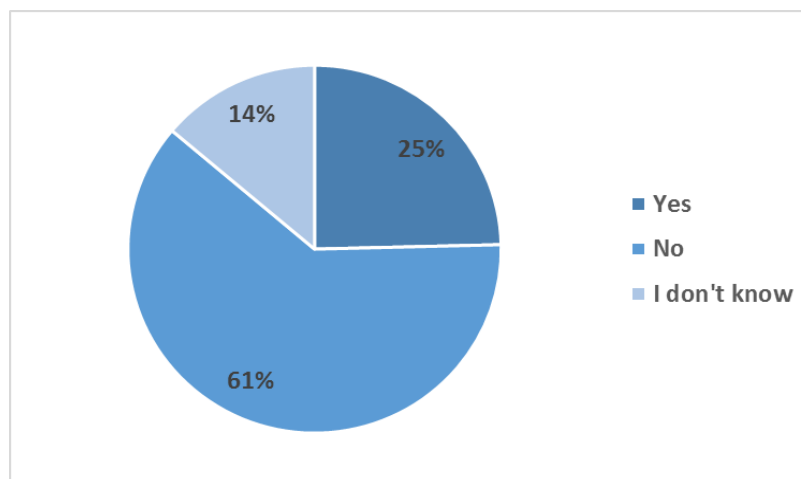
The question 9’s answers distribution reveals the consequence of misunderstanding how introducing risk based thinking concept through ISO management standards affects organizations at large and management process specifically. Most of the responders seem to be convinced that managing risk is an extra-curricular activity – of who is not clear, but surely not of management - that will require diverting resources from other processes. The distribution of answers is presented in Figure 9, below.



**Figure 9. Answers to Question 9.**

*Source: authors*

Question 10 complements question 9 and confirms our conclusion regarding how managers perceive the implications generated by risk management over the process/ processes they manage and at a larger extent, in the context of their responsibilities as managers.



**Figure 10. Answers to Question 10.**

*Source: authors*

Once more, a large majority, 61% of the responders are not aware of having to internalise risk management, that way that they could reach organisational objectives while converting risks into opportunities. Adding to this number the 14% of the ones not knowing we end up with 75% of managers not being aware that processes need to be reengineered in order first to implement the change and then take advantage of the benefits (Figure 10).

## **6. CONCLUSIONS, IMPLICATIONS AND SCOPE FOR FUTURE RESEARCH**

Given the findings of our research, it is perceived that not having a designated management representative, the quality management system would not be properly managed. The main concern is that taking responsibility as a managerial team would lead to less control, less and less organisational objectives achievement, lack of responsibility, involvement and responsibility in an accountable manner.

The results concerning introduction of risk-based approach show that managers tend to be oblivious regarding the shift in the economic paradigm and completely unprepared to understand and adopt

this change. Most of the managers are unprepared for it and, even worst, unwilling to understand it and adopt it. They go as far as considering it as not beneficial for their organisations. Moreover, results show that, in their opinion, there is an abyss between general management and risk management. The proactive attitude of management toward risks associated to organisational objectives is almost unknown, since, in their vision changing attitude and approach regarding risks is not important as to improve the quality performance of the organisation. The implications of such lack of managers' preparedness will, most likely, translate into lower organisational performance.

As with regard to the third change analysed, it came as a surprise result of the research that despite considering procedures as a barrier for innovation, when those are less required, some persons fear that they'll be able to cope without them. The implications of such concern even go as far as to believe that without procedures organisations would fail to reach their objectives, fall behind competition and eventually collapse.

What is really worrying, about the results, is that presumably the ones that answered "I don't know" will just toss a coin to decide the future of their business. Same time, those responses opens up future research directions on issues related to leadership, accountability of the top management team, importance of written procedures over organisational performance.

## REFERENCES

- Ahire, S., L., Landeros, R. & Golhar, D., Y. (1995). Total quality management: a literature review and an agenda for future research. *Production and Operations Management*, 4, 277–306. doi:10.1111/j.1937-5956.1995.tb00057.x.
- Bakotić, D. & Rogošić, A. (2015). Employee involvement as a key determinant of core quality management practices. *Total Quality Management & Business Excellence*, 28 (11-12), 1209-1226. doi: 10.1080/14783363.2015.1094369.
- Dubey, S., S. & Kumar, A. (2017). Literature Review on Implementation of Total Quality Management. *International Research Journal of Engineering and Technology*, 04 (02), 1839-1843. Retrieved August 12, 2017, from <https://www.irjet.net/archives/V4/i2/IRJET-V4I2362.pdf>.
- Harris, C., R. (1995). The Evolution of Quality Management: An Overview of the TQM Literature. *Canadian Journal of Administrative Sciences*, 12, 95–105. doi:10.1111/j.1936-4490.1995.tb00649.x.
- Irimie, S., ISO-IEC (2013). *ISO/IEC 27001:2013 Information technology – Security techniques – Information security management systems – Requirements*. International Organization for Standardization & International Electrotechnical Commission, Geneva, Switzerland: ISO.
- ISO (2009). *ISO 31000:2009 Risk Management – Principles and guidelines*. International Organization for Standardization Geneva, Switzerland: ISO.
- ISO (2015). *ISO 9001:2015 Quality Management Systems. Requirements*. International Organization for Standardization, Geneva, Switzerland: ISO.
- ISO (2016). *ISO 9001:2015 for Small Enterprises – What to do?*. International Organization for Standardization, Geneva, Switzerland: ISO.
- ISO (n.d.). *Risk-based thinking in ISO 9001:2015*. International Organization for Standardization, Geneva, Switzerland. Retrieved August 24, 2017, from [https://www.accredia.it/UploadDocs/5958\\_Risk\\_Based\\_thinking\\_in\\_ISO\\_9001\\_2015\\_Paper.pdf](https://www.accredia.it/UploadDocs/5958_Risk_Based_thinking_in_ISO_9001_2015_Paper.pdf).
- ISO (September, 2015). *ISO 14001:2015 Environmental management systems. Requirements with guidance for use*. International Organization for Standardization Geneva, Switzerland: ISO.
- Kelemen, M., L. (2003). *Managing Quality*. London, UK: Sage.

- Matthews, R., L. & Marzec, P., E. (2015). Continuous, quality and process improvement: disintegrating and reintegrating operational improvement? *Total Quality Management & Business Excellence*, 28 (3-4), 296-317. doi: 10.1080/14783363.2015.1081812.
- Naden, C. (2016, November 15). *Guidance for SMEs using ISO 9001 for quality management just released*. Retrieved June 10, 2017, from <https://www.iso.org/news/2016/11/Ref2138.html>.
- Pirsig, R., M. (1974). *Zen and the art of motorcycle maintenance : an inquiry into values*. London, UK: Bodley Head.
- Raja Sreedharan, V., Raju, R. & Srivatsa Srinivas, S. (2015). A review of the quality evolution in various organisations. *Total Quality Management & Business Excellence*, 28 (3-4), 351-365. doi: 10.1080/14783363.2015.1082421.
- Risk management careers. (2016). In *Institute of Risk Management*. Retrieved June 25, 2017, from <https://www.theirm.org/the-risk-profession/risk-management-careers/>.
- Savic, M., Djordjevic, P., Milosevic, I., Mihajlovic, I. & Zivkovic, Z. (2016). Assessment of the ISO 9001 functioning on an example of relations with supplier's development: empirical study for transitional economy conditions. *Total Quality Management & Business Excellence*, 28, (11-12), 1285-1306. doi: 10.1080/14783363.2015.1135727.
- Verbano, C. & Venturini, K. (2013). Managing Risks in SMEs: A Literature Review and Research Agenda. *Journal of Technology Management & Innovation*, 8 (3), 186-197. doi: 10.4067/S0718-27242013000400017.
- Verboncu, I. & Irimie, S. (2016). Restructuring vs reengineering. *Quality-Access to Success*, 17 (151/April), 39-46.
- Zeininger, L. & Irimie, S. (2015). Aspects of Risk Management Introduction in Small and Medium Enterprises, *Risk in Contemporary Economy*, 200-209. Retrieved June 10, 2017, from <http://www.rce.feaa.ugal.ro/images/stories/RCE2015/Management-Marketing/ZeiningerIrimie.pdf>.
- Zeininger, L. & Mihai, M. (2016). Risk Management and SME's: Needs, Attitudes, Competencies. *Risk in Contemporary Economy*, 179-186. Retrieved June 10, 2017, from <http://www.rce.feaa.ugal.ro/images/stories/RCE2016/IrimieZeiningerMihai.pdf>.
- Zeininger, L., Irimie, S. & Mihai, M. (2016). Romanian SME's face-to-face with risk management. In V. Cantino, P. De Vincentiis, G. Racca (Eds.), *Risk management: perspectives and open issues. A multi-disciplinary approach* (pp. 345-355). London, UK: McGrawHill Education.