Asigurarea Calitatii - Quality Assurance, ISSN 1224-5410 Vol. XXIV, Issue 94, April-June 2018 Pages 29-40

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

Colin SMITH¹, Athanassios KOUROUKLIS², Michele CANO²

¹ SPXFlow, Scotland, UK; ² University of the West of Scotland, Paisley, Scotland, UK michele.cano@uws.ac.uk

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 riskbased 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

References:

- [1] Asharadmin. (2015). "Risk-based Thinking" in ISO 9001 A Controversial Subject!. Available: http://www.larnacamanagement.com/risk-based-thinking-in-iso-9001-a-controversial-subject/. Last accessed 09 Oct 2016.
- [2] Borghesi et al (2013). Risk Management How to Asses Manage and Transfer Critical Risks. Italy: Springer. p19.
- [3] BS EN ISO 9001(2015) Quality Management Systems Requirements. Chiswick High Road London: BSI Standards Publication.
- [4] Cochran, C (2015). ISO 9001:2015 in Plain English. United States of America: Paton Professional. p5.
- [5] Creswell, J. (2007). Qualitative Inquiry and Research Design Choosing Among Five Approaches. 2nd ed. California: Sage Publications. p. 37.
- [6] Creswell, J. (2014). Research Design. California: Sage Publications. p. 4-16.
- [7] Dale, B. et al. (2008). Managing Quality. 5th ed. Oxford: Blackwell Publishing. P60-80.

Asigurarea Calitatii - Quality Assurance, ISSN 1224-5410 Vol. XXIV, Issue 94, April-June 2018 Pages 29-40

- [8] DeSain, C. (2007). Risk-based Management Systems, What Are We Waiting For. Available: http://www.bioprocessintl.com/wp-content/uploads/bpi-content/070305ar02_77249a.pdf. Last accessed 05 April 2017.
- [9] Guest, G. Bunce, A. Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and validity. Field Methods. 18 (1), p. 59-82.
- [10] Hopkins, P. (2017). Fundamentals of Risk Management. 4th ed. Great Britain: Kogan Page. p. 159-411.
- [11] IPA@BBK. (2017). Interpretative Phenomenological Analysis. Available: http://www.ipa.bbk.ac.uk/about-ipa. Last accessed 26 July 2017.
- [12] ISC. (2014). ISO 9001 2015 Is it a Big Challenge for Auditors?. Available: http://isc-worldwide.com/9001-2015-is-it-a-big-challengefor-auditors/. Last accessed 09 Oct 2016.
- [13] ISO subcommittee responsible for ISO 9001. (2015). ISO 9001:2015 Risk-based thinking. Available: http://www.sciqual.com.au/sites/default/ files/iso_9001-2015_-_risk_based_thinking.pdf. Last accessed 29 Mar 2017.
- [14] ISO. (2015)a. Correlation matrices between ISO 9001:2008 and ISO 9001:2015. Available: http://isotc.iso.org/livelink/fetch/2000/2122/-8835176/-
- 8835848/8835872/8835883/ISO%209001Correlation Matrices.doc. Last accessed 02 April 2017.
- [15] ISO. (2015)b. Implementation Guidance for ISO 9001:2015. Available: https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso9001implementation_guidance.pdf Last accessed 02 April 2017.
- [16] ISO. (2015)c. ISO 9000 Quality management. Available: http://www.iso.org/iso/home/standards/management-standards/iso_9000.htm. Last accessed 26 Sept 2016.
- [17] ISO. (2015)d. ISO 9001:2015 Risk-based thinking. Available: http://www.iso.org/iso/iso9001implementation guidance.pdf. Last accessed 02 April 2017.
- [18] ISO. (n.d.). ISO 31000 Risk management. Available: https://www.iso.org/iso-31000-risk-management.html. Last accessed 05th April 2017.
- [19] ISO.Org. (2015). ISO 9001:2015 How to use it. Available: http://www.iso.org/iso/iso_9001-2015 how to use it.pdf. Last accessed 09 Oct 2016.
- [20] Kumar, R. (2014). Research Methodology. 4th ed. London: Sage Publications. p. 213-248
- [21] LRQA. (2015). Preparing for ISO 9001:2015. Available: http://www. lrqa.co.uk/standards-and-schemes/iso-9001/training/iso-9001-2015-trainingcourses.aspx. Last accessed 21 May 2017.
- [22] Purdy, G. (2010). ISO 31000:2009 Setting a New Standard for Risk Management. Risk Analysis an International Journal. 30 (1), p. 886.
- [23] Seear, D. (2015). ISO 9001:2015 into the Future. Bloomington: Author House. p. 236.
- [24] Shuff, M. (2015)a. ISO 9001:2015 The likely impact (Part II). Available: https://www.cognidox.com/2015/02/iso-90012015-the-likely-impact-part-ii/. Last accessed 24 May 2017.
- [25] Shuff, M. (2015)b. ISO9001:2015 How to Apply Risk-based Thinking to Quality Processes. Available: https://www.cognidox.com/2015/08/whitepaper-how-to-apply-risk-based-thinking-to-iso-90012015/. Last accessed 15 April 2017.
- [26] Statistics Canada. (2013). Non-probability sampling. Available: http://www.statcan.gc.ca/edu/power-pouvoir/ch13/nonprob/5214898-eng.htm. Last accessed 18th April 2017.
- [27] The Chartered Institute of Internal Auditors. (2017). Glossary. Available: https://www.iia.org.uk/resources/global-guidance/international-standards/glossary/. Last accessed 07 Jul 2017.
- [28] Wilson J.P., Campbell L. (2016) "Developing a knowledge management policy for ISO 9001: 2015", Journal of Knowledge Management, Vol. 20 Issue: 4, pp. 829-844

Asigurarea Calitatii - Quality Assurance, ISSN 1224-5410 Vol. XXIV, Issue 94, April-June 2018 Pages 29-40

[29] WordPress (2011). Risk Management Resistance. Available: https://whereswinky.wordpress.com/2011/11/. Last accessed 08 April 2017.