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ISO 9001:2015 Quality Management System Standard

After three years of revision work by experts from nearly 95 participating and observing countries, the ISO 9001:2015 standard has finally been released.

Acting ISO Secretary-General Kevin McKinley explains “ISO 9001 allows organisations to adapt to a changing world. It enhances an organisation’s ability to satisfy its customers and provides a coherent foundation for growth and sustained success.” You can see a video on YouTube, where Kevin McKinley talks about the new standard. <https://www.youtube.com/embed/Lp6xP-We5yY?fs=1&autoplay=1&rel=0>

Nigel Croft, Chair of the ISO subcommittee that developed and revised the standard, said, “We are just bringing ISO 9001 firmly into the 21st century. The earlier versions of ISO 9001 were quite prescriptive, with many requirements for documented procedures and records. In the 2000 and 2008 editions, we focused more on managing processes and less on documentation. We have now gone a step further and ISO 9001:2015 is even less prescriptive than its predecessor, focusing instead on performance. We have achieved this by combining the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organisation.”

ISO 9000, which lays down the concepts and language used throughout the ISO 9000 family of standards has also been revised and a new edition is available.

Although managing risk has always been an aspect of the standard, the new standard has managing risk as key element. To help you, BSI have published a whitepaper “The

importance of risk in quality management”. This paper covers:

- Why is managing risk important in a quality management system?
- How is risk being incorporated into the new ISO 9001:2015 standard?
- What are the benefits of managing risk?
- What does this mean and how can you prepare?

<http://www.bsigroup.com/LocalFiles/en-GB/iso-9001/Revisions/BSI-ISO-9001-The-importance-of-risk-in-quality-management-UK-EN.pdf?>

The BSI have also developed a range of support tools including:

- A Transition Guide that provides an overview of the new High Level Structure and the requirements of the new standard.
- A Self-Assessment Questionnaire that helps you assess your organisation’s readiness for a certification assessment and identify any gaps
- A mapping guide that provides an overview of the changes, deletions and new or enhanced requirements between the 2008 and 2015 standards

These are available from the BSI Website www.bsigroup.com

ISO 9001 Based Sector Standards

Many industrial sectors have developed their own standards that are based on ISO 9001 but are targeted on the requirements of the sector e.g. automotive, aerospace and medical devices. These standards are also being reviewed in the light of the ISO 9001 revision.

The revision of the *ISO 13485 Medical devices – Quality Management systems – requirements for regulatory purposes* standard has just reached the Final Draft stage. Wil Vargas, Secretary of ISO/TC 210, the technical committee responsible for the revision, said

"This International Standard will help to ensure there is global harmonization of the regulatory requirements for quality management systems in the sector, and reassure stakeholders that the requirements are being met, at every stage of the product's life cycle." It is due to be published early in 2016.

Another very popular sector specific standard based on ISO 9001 is the ISO/TS 16949 standard for the automotive sector. The International Automotive Task Force (IATF) has set up a working group of IATF member organizations "to develop a design specification for the revision of ISO/TS 16949 to align with the ISO 9001:2015 based structure and requirements." The IATF assigned work team will be seeking stakeholder inputs on potential enhancements to the ISO/TS 16949 standard. In addition, customer requirements are being analyzed for potential inclusion in the future standard. Completion of the revised quality management system standard is targeted for the fourth quarter of 2016.

ISO 14001 Environmental Management System Standard

As if one revision wasn't enough to deal with, the revised ISO14001 standard was released shortly before the ISO 9001 release. Both standards have the same structure and are based on Annex SL which eventually will be the framework for all the management standards.

ISO 14001:2015, *Environmental management systems. Requirements with guidance for use*, has been revised to help put environmental management at the heart of business processes and objectives, continue to help organisations meet regulatory requirements, and save money and resources. ISO 14001:2015 responds to the latest trends, such as an increasing recognition by companies of the need to factor in both external and internal elements that influence their impact, including climate volatility. Other key improvements in the new version include:

- A greater commitment from leadership

- An increased alignment with strategic direction
- Greater protection for the environment, with a focus on proactive initiatives
- More effective communication, driven through a communications strategy
- Life-cycle thinking, considering each stage of a product or service, from development to end-of-life

Anne-Marie Warris, Chair of the technical committee that developed the standard said, "ISO 14001 has fulfilled many of the dreams we foresaw over the last 20 years, including helping people to manage all their environmental issues in a holistic manner. Looking forward, the new version will help with a stronger integration between environmental issues and an organisation's strategic action planning and thinking. I foresee the life-cycle perspective and supply chain issues embedded in ISO 14001 becoming stronger in the future."

Again, BSI have provided a range of tools to support the transition and these can be found on the BSI website www.bsigroup.com.

New People Management Standard

One of the seven management principles is the engagement of people and this principle is embedded in both the quality and the environmental management system standards. However, now there is a new standard that has been developed and released by British Standards that focuses on people; *BS 76000 – Human resource – Valuing people – Management system – Requirements and guidance*. It is the first national standard to recognise the importance of valuing people in an organisation.

According to BSI, the standard is based on the premise that people are an organisation's biggest asset and should be treated as such - so the organisation gets the most out of them and they get the most out of their working life. BS 76000 is a principles-based management system standard which provides a framework to develop a more equal and sustainable relationship between organisations and people who work for them.

The standard is relevant for any organisation beyond that of sole trader, not just those with large HR departments, but any organisation that employs people.

Further details can be found from the BSI website www.bsigroup.com

ISO Survey of the Use of Standards

An annual survey is undertaken to understand the uptake and use of management standards. The 2014 results show that the growth in certification to ISO 9001 and ISO 14001 has stabilised with ISO 9001 showing just a small growth of 1%, whilst ISO 14001 has grown by 7%. It is expected that the release of the new revisions of these standards may give them an additional impetus for growth.

The two standards showing the most growth are the energy management standard (ISO 50001) with 40% growth and the food management standard (ISO 22000) with 14% increase.

For further details on the survey, please visit www.iso.org

Status of the New Health and Safety Standard

The OHSAS 18001 standard is planned to be replaced by the ISO 45001 Health and Safety Management System standard. An important committee meeting was held recently where representatives from the ISO and the International Labour Organisation (ILO) met in Geneva to work through comments and issues raised during the Committee Draft consultation stage of its development. These issues have now been resolved and the standard is now moving on to the Draft International Standard stage.

Kevin McKinley, ISO Acting Secretary-General, said, "It is a positive step as the standard will ultimately be a very useful tool to help organisations save lives and protect the health and safety of their employees. The health and safety of workers is a fundamental issue for all organisations. ISO's work in this area is an important complement to the International Labour Standards of the ILO.

There has been significant interest in ISO 45001 to build on existing ILO and national mechanisms to further enhance worker protection. We are delighted that, following these meetings, we are one step closer to publication."

ISO 45001 is due to be published in October 2016. For further information please visit the ISO website www.iso.org

World Standards Day

The theme for the 2015 Standards Day that was celebrated last month was "Standards – The world's common language". According to the ISO, the IEC and the ITU, the reasons for choosing this theme was because international standards:

- Make communication across countries and technology possible
- Help us understand important information despite language barriers
- Are necessary for interoperability and compatibility of technology
- Help us get exactly what we want
- Are necessary for co-operation between people

A short video was released to help people imagine what a world without standards would look like. You can view the video at https://www.youtube.com/watch?v=Mpt5_RsLH6o