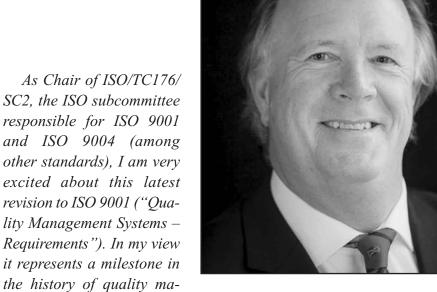
ASIGURAREA CALITĂȚII – QUALITY ASSURANCE

Iulie – Septembrie 2015 Anul XXI Numărul 83

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



nagement, 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". If we think back to the state of the art of technology a mere 15 years ago (when the last major revision to ISO 9001 was

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

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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.

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.