Azzur Labs, LLC

ISO 9001 COMMUNITY BRACES FOR MAJOR REVISIONS IN 2015

More than 1.2 million organizations world-wide are ISO 9001 certified, making it the world's most popular standard for quality management. Every five years, all ISO standards are reviewed to make sure they are still current and relevant in the marketplaces they serve. Currently ISO 9001 is under review, with an updated version due to be available in September of 2015. Although this will be the first update since 2008, it is really the first major revision since the ISO 9001:2000 version consolidated three previous standards (ISO 9001, ISO 9002, and ISO 9003).

Key Differences

While still nearly a year from scheduled publication, initial drafts of the new ISO 9001:2015 standard place emphasis on modifying the existing standard in these specific areas and concepts:

Structure: The new revision introduces a common structure and expands the number of sections from eight to ten, with additions for performance management and evaluation. By following this structure, commonly referred to as the HLS or Annex SL, organizations will be able to cross reference and align with the other management system standards much more easily than in previous versions. The requirements primarily remain the same, but will actually be less rigid.

Risk Management: Movement away from the classic "Corrective/ Preventive Action" model in the new revision has been noted. To expand the more limited view of finding the "root cause" of a problem and applying a permanent solution, the new structure takes a risk-based approach, examining system-wide risks which could be of greater concern to the organization and the broader bases they serve. This could include the community, employees, vendors, regulators and more. Organizations will not be required to do a formal risk assessment, but will be asked to consider risk as integral to the quality management system as a whole.

The new ISO 9001:2015 standard places emphasis on modifying the existing version in these specific areas and concepts:
Structure
Risk Management
Process Approach
Terminology

Process Approach: The requirement to use the process approach has been made more overt by adding a specific new clause. The "Plan-Do-Check-Act" methodology is to be applied to all processes and the quality management system as a whole. The intent is to keep the current focus on managing processes as an effective method to gain a more repeatable pattern of success, and to remain more applicable to a wider array of businesses.

Terminology: Multiple changes on this front that may take some getting used to for long-time ISO practitioners. The terms "Documents" and "Records" will be replaced by "Documented Information"; "Product" will be "Goods and Services"; "Continual Improvement" is now simply "Improvement"; "Management Responsibility" will be "Leadership" ; "Product Realization" will be replaced by "Operation". Gone altogether are the terms "Exclusions" and "Preventive Actions". And a "Quality Manual" is no longer required, but will fall under the broader requirement for "Documented Information". This does not mean that organizations with an existing quality manual need to do away with it or make other major changes. There's simply more flexibility to meet the requirement that relevant information is retained and available when necessary.

Clearly there may be more changes and much work to be done, but organizations currently certified to ISO 9001:2008 will have a three-year transition period to certify to ISO 9001:2015 once the standard has been published. However, because the new requirements depend on the context of each organization, and there will be a number of ways to comply with the different clauses, smaller organizations, ser vice industries and other non-traditional businesses should find ISO 9001:2015 more practical and simpler to use once implemented.

About the Author:

Frank Rocchino has over twenty years of experience in quality systems, safety and management. He implements and manges the corporate regulatory compliance initiatives at Azzur Labs and assures international compliance with governing agencies and client specifications.

He holds a Bachelor of Science in Chemistry and is a certified Six Sigma Green Belt, ISO internal auditor, Occupational Safety and Health Supervisor and trainer.

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