What is ISO 9001?
The ISO 9001 Quality Management System is the world’s most popular quality improvement standard, with over one million certified organizations in 180 countries around the globe. It is the only standard in the 9000 family of standards published by the International Organization for Standardization (ISO) that can be used for the purpose of conformity assessment. ISO 9001 also serves as the basis for many other important sector-specific standards, as well as widely used management system standards such as OHSAS 18001 and ISO 14001.

ISO 9001 Revision
The International Organization for Standardization (ISO) is working on a major revision of the ISO 9001 standard. The last revision dates back to 2008 and introduced a small number of new requirements. Publication of the final version of ISO 9001:2015 is expected at the end of 2015. The working draft, ISO/DIS 9001:2015, is now available, and has a clear objective.

Revision Timeline
The working draft, ISO/DIS 9001:2015 was distributed for review and comment on May 8, 2014. The Committee Draft (CD) published in the run-up to this draft received around 3,000 comments and was approved by 80% of the countries in a preliminary vote. The international community has been invited to submit their comments on this interim working draft by July 2014.

Publication of the official draft international standard (DIS) is expected in September 2014. After the commenting period, the final draft international standard (FDIS) will then be passed before its presentation, scheduled for November 2014. Publication of the final version of ISO 9001:2015 is expected in September 2015.

New Structure
It is certain that a “high-level structure” will replace the existing structure. This structure is in accordance with the requirement of the ISO Directive, Annex SL 2013.
All management system standards developed in the future will use a consistent structure and outline such as identical core texts, common terms and core definitions. This is to ensure that all sections of management system standards share the same section headings and core texts. The ISO 14001 and BS OHSAS 18001 standards will also be revised in accordance with the same structure.

This ISO/DIS 9001:2015 version follows the new high-level structure and comprises ten sections:

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Summary of the Key Changes
The new draft is designed to make the standard more generic and more easily applicable by service industries. Therefore, the term “product” has been replaced by “products and services” when specifically referring to the deliverables for the customer.

Context of the Organization
The high-level structure and the core text established in Annex SL, Appendix 2, have introduced two new clauses related to the context of the organization:
4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties

These two clauses require the organization to determine the issues and requirements that can impact the planning of the quality management system (QMS) and can be used as input for the development of the QMS.

The stakeholder approach, considered one of the most modern corporate governance principles, is new. This approach is based on the assumption that long-term business success can only be ensured by considering the requirements of company stakeholders. The approach has been described for many years in ISO 9004:2009, Section 4.4 “Interested parties, needs and expectations,” and has been introduced in the draft standard. In comparison to “Customer Relationship Management” (CRM), which only addresses the relationship between an organization and its customers, the principle of Stakeholder Relationship Management (SRM) goes significantly further. It tries to balance the relationship of the organization with all, or with the most important, stakeholders/interested parties. These could include direct consumers, suppliers and retailers and other parties along the supply chain, authorities and other relevant interested parties. As a new feature in this draft, the term “interested parties” now also includes owners, people in an organization, bankers and even competitors.

Although this DIS refers to the determination of the requirements of major interested parties, it does not require that products and services have to fulfill the need and expectations of external parties. This is with the exclusion of already mentioned external parties in ISO 9001:2008, i.e. customer and authorities, etc. Such a requirement would require a change in the scope of the standard, which is not covered under the revision.

Process Approach
The ISO 9001:2008 standard promoted the adoption of a process approach when developing, implementing and improving QMS effectiveness. The draft standard does so even more explicitly in Section 4.4 Quality management system and its processes. This sub-chapter lists the essential requirements of a process-focused management approach. Inputs and outputs of each process must be defined. In the future, the standard will require the measurement of performance indicators and the assignment of responsibilities.
Risk and Preventive Actions
The high-level structure and core texts specified in Annex SL, Appendix 2, does not include a clause stating specific requirements for “preventive measures.” The reason is because acting as a “preventive tool” is one of the key purposes of a quality management system (risk prevention). The emphasis on a risk-based approach is referenced in many places in the draft standard, from risk assessment in Section 4.4 “Quality management system and its processes,” leadership issues in Section 5.1.1 and a separate sub-clause in Section 6.1.2 “Actions to address risks and opportunities” to risk-based approaches in “Operational planning and control” (Chapter 8.1) and “Management review” (Chapter 9.3). While the draft demands that risks are identified and acted upon, there is no requirement for standardized risk management.

Documented Information
The term “documented information” replaces the previous terms “documents” and “records.” The intention was to give users more flexibility. This also applies to the description of processes. The organization determines the extent of documented information on processes, depending on factors such as process complexity or employee competence. Documented procedures previously required by the standard are no longer necessary.

Management Responsibilities
The draft standards increase “management responsibilities.” In the future, responsibilities previously held by the Quality Management Representative will rest with top management and a more precise assignment of roles and responsibilities will be required.

Management Review
The scope of the management review is extended by the addition of the aspects “strategic direction of the organization,” consideration of the “relevant interested parties” and “assessment of risks and opportunities” at a strategic level.

How Can You Prepare?
At this stage, it is relatively easy to predict the updated QM-specific contents that will be included in the ISO 9001:2015. The requirements of the above sections will only be subject to minor changes. Organizations that have established management systems should familiarize themselves with the changes and subsequently upgrade their management systems accordingly in 2015 and 2016.

There will be a three-year transition period during which both the old and the new standard will apply in parallel. However, within the scope of certification, organizations should not leave the upgrade until the very end of the transition period. We recommend that organizations upgrade their systems to the new standard at an early stage within the scope of a regular re-certification audit.

How Can We Help You?
TÜV SÜD will continue keep its customers informed about any changes in the ISO 9001 standard. TÜV SÜD employs some of the world’s leading experts in quality management systems and can conduct gap analyses and preliminary audits to help determine your organization’s readiness for ISO 9001 certification.
The TÜV SÜD Certification Mark
The ISO 9001 certification mark from TÜV SÜD demonstrates your compliance towards continuous excellence. The prestige of the TÜV SÜD certification mark also sets your organization apart from other ISO 9001-certified companies and distinguishes your company from your competition.

Your Business Benefits
- **Save money and time** – through quality management practices that increase your organizational efficiency, productivity and profitability.
- **Minimize risk** – by consistently achieving a level of quality defined by the standard, thus ensuring your products and services are less likely to fall short of customer expectations.
- **Profit from an expert partnership** – with TÜV SÜD, an internationally recognised and respected brand.
- **Increase your competitiveness** – with a quality management system certified by TÜV SÜD that attracts investors and lowers trade barriers to your business.
- **Gain market recognition** – with the world’s most widely known quality management system, which can help establish your presence as a supplier when entering a new market.

Why Choose TÜV SÜD?
TÜV SÜD is a global leader in management systems solutions, having issued more than 54,000 management systems certifications to date. Our dedicated and experienced auditors across the globe can speak your language and help you explore the possibility of integrating your ISO 9001 certification initiative with other management systems. We can also act as a one-stop provider for your quality certification needs. With the TÜV SÜD certification mark, you demonstrate your commitment to delivering quality products and services.

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TÜV SÜD is a premium quality, safety and sustainability solutions provider that specialises in testing, inspection, auditing, certification, training and knowledge services. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East and Asia. By delivering objective solutions to our customers, we add tangible value to businesses, consumers and the environment.

Related services
TÜV SÜD provides the following related services:
- ISO 14001 – Environmental management system certification
- ISO 50001 – Energy management system
- ISO/TS 16949 Quality management system certification for automotive
- OHSAS 18001 – Occupational health and safety management system certification
- TL 9000 – Telecommunications
- ISO/IEC 27001 – Information security management system certification
- ISO/IEC 20000-1 – IT service management system certification