



# BROADEN YOUR FOCUS ON QUALITY AND RISK MANAGEMENT

**ISO 9001:2015 TRANSITION TOOLKIT**

# STAKEHOLDER FOCUS AND RISK-BASED APPROACH ARE KEY ELEMENTS IN QUALITY MANAGEMENT: ISO 9001:2015

The publication of ISO 9001:2015 in September 2015 is the final stage in the ISO 9001 revision process. This version will eventually fully replace ISO 9001:2008, though there will be a transition period.

ISO 9001:2015 positions the new version of the standard as an integral part of an organization's efforts towards improving its overall performance. It encourages more internal and external stakeholder focus as part of the adoption of a risk-based approach to quality management and emphasizes the importance of adopting a Quality Management System (QMS) as a strategic decision for an organization.

## THE MAJOR CHANGES THAT ISO 9001:2015 BRINGS ARE:

### ORGANIZATIONAL CONTEXT

The 'context' of an organization (or its 'business environment') refers to the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products and/or services. Consideration of an organization's context must now be an element of the QMS design and implementation process.

### RISK AND OPPORTUNITIES

A vital part of the planning and implementation of a QMS is a new requirement to identify the risks and opportunities that can potentially impact the operation and performance of the QMS, as well as the corresponding 'proportionate' actions to address them.

### LEADERSHIP

Top management are now required to demonstrate a greater direct involvement in the organization's QMS; there is now a focus on 'leadership' rather than just management of the QMS.

### DOCUMENTED INFORMATION

The terms 'documented procedure' and 'record' used in ISO 9001:2008 have both been replaced throughout ISO 9001:2015 by the term 'documented information'. This is defined as information that is required to be controlled and maintained by an organization, though it is up to each organization to determine the level and type of documentation necessary to control its own QMS.

### OTHER QMS REQUIREMENTS

There are also other changes to QMS requirements, including:

- Proposed specific requirements for organizations in relation to the execution of a process approach when planning, implementing and developing a QMS
- Identification of the competence necessary for personnel doing work that affects its quality performance
- Identification and maintenance of the knowledge needed to ensure that an organization can achieve conformity of products and services
- A risk-based approach to ascertain the type and extent of controls suitable to all types of external provider

### STRUCTURE AND TERMINOLOGY

ISO 9001:2015 adopts the clause structure specified in Annex SL, which is now the required framework for all new and revised ISO Standards. The stated intention behind this is to ensure that ISO 9001 is aligned with other management systems standards and to present QMS requirements in a more consistent, rational manner.

It is important to note that for those organizations that already have an ISO 9001 compliant QMS, there will be no requirement to change their existing QMS procedure and document structure, or the terminology they use, to mirror that specified in ISO 9001:2015.

### SGS SOLUTIONS FOR A SMOOTH TRANSITION

As the world's leading certification body and a professional learning and development organisation, we offer you a variety of solutions during the transition process. We are in an ideal position to support you through this transition process whether you are an SME or an global organisation.

### TRAINING:

As part of our training portfolio for ISO 9001:2015, we have developed several courses to assist you in managing your own transition:

- **Annex SL:** We will help you understand the high level structure of the new framework and how integration with other management system standards is becoming more efficient.
- **ISO 9001:2015:** An introduction to the changes in the new version and explains how this will impact your existing system.
- **Risk-Based Thinking:** A course covering the principals that support the identification of risk and opportunities and the different techniques/methodologies needed to address them.

- **Empowering Leadership:** A two day workshop addressing the skills needed by those operating in Quality, Environmental and Health and Safety roles for the forthcoming evolution of management systems standards and their respective commercial impacts.

#### **NEEDS ASSESSMENTS:**

Our experts can carry out a gap analysis against the new requirements to make your transition smooth and transparent. This provides your organisation with structured assistance by highlighting the extent that your existing systems and controls cover the requirements of ISO 9001:2015 and by identifying an implementation action plan where you need it.

#### **ISO 9001 CERTIFICATION**

SGS will, of course, now be offering ISO 9001:2015 certification to both new and existing clients.

#### **ISO 9001:2008 TRANSITION**

Organizations which are already certified to ISO 9001:2008 will have three years from formal publication of ISO 9001:2015 in which to transfer to the new version of this standard. Based on the current publication schedule, this transition period would end in September 2018.

#### **WHY SGS?**

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 85,000 employees, SGS operates a network of over 1,800 offices and laboratories around the world.

We are constantly looking beyond customers' and society's expectations in order to deliver market leading services wherever they are needed. We have a history of undertaking and successfully executing large-scale, complex international projects. With a presence in every single region around the globe, our people speak the language and understand the culture of the local market, and operate globally in a consistent, reliable and effective manner.

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For an optimal transition towards ISO 9001:2015 contact [certification@sgs.com](mailto:certification@sgs.com) or visit [www.sgs.com/iso9001-2015transition](http://www.sgs.com/iso9001-2015transition)

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**WHEN YOU NEED TO BE SURE**

**SGS**