



**ISO 9001:2015 - UPDATE ISO 9001:2015 ISSUED**

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.

This document aims to provide an insight into the contents of ISO 9001:2015. It is not intended to be a full explanation of all of the requirements contained within it, rather it provides an overview of the key changes to Quality Management Systems (QMS) that have been introduced.

## **SUMMARY**

ISO 9001:2015 positions the new version of the Standard as an integral part of an organization's efforts towards the broader aim of sustainable development and promotes it as a tool for improving an organization's overall performance. It encourages more internal and external stakeholder focus as part of the adoption of a risk-based approach to quality management and emphasises the importance of adopting a QMS as a strategic decision for an organization.

In addition to renaming and repositioning some QMS activities, other significant new requirements have been introduced. Some of these are a consequence of the adoption of the Annex SL framework and core text now required to be used for all new and revised ISO Management Systems Standards, but others are specific QMS requirements.

## **ORGANIZATIONAL CONTEXT**

The 'context' of an organization (sometimes called 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. As a result, the design and implementation of an organization's QMS will be influenced by its context. An organization's context will include, for example:

- The specific objectives of the organization
- The needs and expectations of its customers and any other relevant 'interested parties'
- The products and services it provides
- The complexity of both the processes that the organization uses and the way in which they interact
- Its size and organizational structure

## **LEADERSHIP**

Top management are now required to demonstrate a greater direct involvement in the organization's QMS and the absence from ISO 9001:2015 of the need for a specific 'Management Representative' is partly an attempt to ensure that 'ownership' of an organization's management system is not simply focused on one individual. There is now an emphasis on 'leadership' rather than just management of the QMS.

## **RISKS AND OPPORTUNITIES**

Although 'planning' has long been a familiar requirement of any QMS, ISO 9001:2015 now places a greater emphasis on the planning that an organization does which is integral to its business. An organization is now required to consider both its 'context' and 'interested parties' when planning and implementing its QMS.

An essential part of that process is a

new requirement for organizations to identify those risks and opportunities that have the potential to impact (negatively or positively) on the operation and performance of their QMS. Having identified those external and internal issues that are relevant to its context, as well as the needs of interested parties, an organization is required to use that information to determine both the risks and opportunities associated with them, as well as the "proportionate" action that needs to be taken to address them.

It is important to note, however, that although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process; organizations are free to choose the assessment and evaluation mechanism they consider is most appropriate for them.

## **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 should be noted that it is up to each organization to determine the level and type of documentation necessary to control its own QMS, based upon:

- The size of organization and its type of activities, processes, products and services
- The complexity of processes and their interactions
- The competence of organizational personnel

Where ISO 9001:2008 currently refers to documented procedures (e.g. to define, control or support a process) this is now expressed within ISO 9001:2015 as a requirement to 'maintain' documented information. Where ISO 9001:2008 now refers to records, this is now expressed as a requirement to 'retain' documented information.

**OTHER QMS REQUIREMENTS**

In addition, there are other changes to QMS requirements, though some are more significant than others. These include those highlighted below.

ISO 9001:2015 proposes specific requirements for organizations in relation to the way in which they apply a process approach when planning, implementing and developing to their QMS; these include as a list of requirements identifying the essential elements of such an approach. The stated intention is to ensure that organizations systematically define and manage not just their processes, but also the interaction between them.

Organizations will have to identify the competence necessary for personnel doing work that affects its quality performance, as well as ensuring that those personnel are competent to do so. Competence would be defined as the "ability to apply knowledge and skills to achieve intended results".

There is now a specific requirement to identify and maintain the knowledge needed to ensure that an organization can achieve conformity of products and services. This 'organizational knowledge' includes that held by personnel, intellectual property, production methods, etc.

Organizations are required to take a risk based approach to determine the type and extent of controls appropriate to all types of external provider. This covers all external provision of goods and services, including those who supply raw materials, components, etc. and those to whom processes and functions are outsourced.

Although there is no longer any specific requirement for preventive action, organizations will still be required to identify opportunities for improvement, including those designed to prevent nonconformities. In part, this covered under the requirements relating to Risks and Opportunities referenced above.

**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 reason for this is to ensure that ISO 9001 is aligned with other management systems standards. By utilizing the Annex SL structure it is intended to present QMS requirements in a more consistent, rational manner and not simply offer a template for the elements of an organization's QMS.

There are also some changes in the terminology used in ISO 9001:2015, which differ from that used in the 2008 version.

| ISO 9001:2008             | ISO 9001:2015  |
|---------------------------|--|
| 'Products'                | 'Products and services'                                |
| 'Documentation' 'Records' | 'Documented information'                               |
| 'Work environment'        | 'Environment for the operation of processes'           |
| 'Purchased product'       | 'Externally provided processes, products and services' |
| 'Supplier'                | 'External provider'                                    |

It is important to note that for those organizations which 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 used in ISO 9001:2015

**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.

# SGS SOLUTIONS FOR A SMOOTH 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.

## 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 proposed 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 organization 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 9001:2015 CERTIFICATION:

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

## 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.

## FOR MORE INFORMATION

Further information and updates on ISO 9001:2015 will be made available by SGS in the future. However, if you have any immediate questions relating to Certification, or the help and assistance that SGS can provide, please [contact your local SGS office](#).

Additional information is also available via the following link:

[BrainShark webinar](#)

[ISO 9001:2015 and Risk-based thinking webinar](#)

---

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)

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

WHEN YOU NEED TO BE SURE

SGS