

## ISO 9001:2008

ISO 9001 was revised during 2008 and published in November 2008. If you require a summary of the changes to the Standard, please refer to ISO 9001:2008 Annex B. The table in Annex B details the changes between ISO 9001:2000 and ISO 9001:2008.

As with most Management Standards there is a need to interpret the requirements of the standard with regard to the requirements of your business. Many of the changes to ISO 9001 are subtle word changes, which may or may not have implications for your system. The changes the Standard may effect on your system will depend on your business, the maturity of the Quality Management System and how well your system has adopted a process based approach.

Some of the most significant changes identified are as follows:

1. Clause 0.1 states:  
The design and implementation of an organization's quality management system is influenced by
  - a) its organizational environment, changes in that environment and the risks associated with that environment.

*Risk is a term that has a stronger emphasis in the revised standard and therefore the implication that there is a need for risk management.*
2. Clause 6.3 states an organization should "determine, provide and maintain the infrastructure needed to achieve conformity to product requirements". Infrastructure has been extended to include 'information systems'.
3. Clause 7.2.1 includes additional requirements for post delivery activities, e.g. warranties and maintenance. There is a requirement to consider this when identifying the customer's requirements prior to supplying a product.
4. Clause 7.5.4 states that customer property can include intellectual and personal data.

*The addition of "personal data" will be significant for most organizations when you consider personal data is regarded as any data that allows you to identify a person, e.g. name and address.*

*Organizations should consider how they control access to personal data, the transfer of personal data and how long data is stored. There is there a need to demonstrate compliance with the Data Protection Act, e.g. registering with the Information Commissioner's office and auditing to demonstrate compliance.*

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5. Clause 7.6 has changed the term "device" to "equipment"

*This may be a minor change for an organization, i.e. calibration of measuring equipment, determining the monitoring and measurement to be undertaken and may already be well controlled.*

There are a number of other clauses, which require consideration to ensure the possible implications to your business have been thoroughly examined. Some of these clauses include:

1. Clause 4.1 defines outsourced processes and states that an organization is responsible for managing its outsourced processes and therefore for implementing adequate controls to manage the outsourced processes to ensure conformity of the product (or service) provided.

2. Clause 4.2.1: A note has been added which states:

A single document may address the requirements of one or more procedures. A requirement for a documented procedure may be covered by one or more document

*For example, an organization may choose to merge the procedures for managing corrective and preventive actions within one documented procedure. Conversely, where there is a requirement for a procedure to control nonconforming product this may be covered by various processes such as complaints, corrective actions, etc.*

3. Clause 8.2.1 which relates to monitoring the perception of customer satisfaction has added a note to provide examples to organizations about the type of data that can be gathered to gain information about the level of satisfaction the customer has with the product.

The changes to ISO 9001:2008 are open to interpretation by each organization. As you can imagine from reading the list above detailing some of the more significant changes there will be other clauses, which may impact your business. If you need further advice or assistance in upgrading your system, EQM Ltd is practised at providing solutions that are designed to meet the needs of your business.

We will be hosting a number of workshops in the near future. If you would like to register your interest to attend a workshop, please complete an Enquiry Form by selecting the link below.