

ISO 9001:2008

Introduction

ISO 9001, like all standards is subject to periodic review to determine whether it is still relevant, whether it needs to be updated or whether it should be discarded. The review period is around 5 – 6 years so, since the current version was issued in the year 2000, the standard is due for revision and re-issue.

The revision process for ISO 9001 is designed such that whenever there are significant changes to be made (major revision), the next revision will be less significant (minor). Since the revisions issued in 2000 were major, it follows that the next one will be minor. Indeed, the proposed changes are more based on the clarification of points already in the standard rather than the inclusion of new requirements.

However, the proposed changes to ISO 9001's 'sister' standard, ISO 9004, are much more significant though this is only a 'guidance' document rather than a requirements standard.

The Change Process

When ISO 9001 undergoes changes there is a standard process which is usually followed. The standard is reviewed by various working groups and committees and suggestions are put forward for amendments. These amendments are incorporated into a draft version of the standard which is known as a Committee Draft (CD), there may be more than 1 CD in which case they are sequentially numbered e.g. CD1, CD2, etc. Formal feedback to the CD's can be submitted by anyone.

Following feedback to the CD's, a Draft International standard (DIS) is published and this is followed by the Final Draft International Standard (FDIS) normally represents what the finished standard will look like barring punctuation errors etc.

ISO 9001 Changes

The following changes have been made to ISO 9001 in the DIS:

Section	Changes
0.1 Para. 3	Statement of where and who can use the standard now includes statutory requirements as well as customer and regulatory and clarifies that these requirements are restricted to those applicable to the product
0.4	A comment has been added that the development of ISO 9001:2008 made due consideration to ISO 14001:2004
1.1 & 1.2	Again, statutory requirements have been added (as in 0.1) and Note 1 has been amended to include comments regarding purchased product as well as product from realisation processes. Note 2 has been added explaining that statutory and regulatory requirements may be expressed as legal requirements
2	The reference to ISO 9000 now states the fact that is at version 2005
3	The explanation of who the 'customer', 'organisation' and 'supplier' are, has been removed
4.1	a) The word 'identify' has been replaced with 'determine' The statement regarding outsourced processes has been slightly re-worded but the intent is the same. Note 2 has been added to reflect the fact that outsourced processes may be linked to clause 7.4 (purchasing) and Note 3 expands on the type of control that may be applied to outsourced processes in order to ensure control over them

4.2.1	The wording has been slightly re-modelled but the intent stays the same. Note 2 has been added to clarify that a single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. e.g. you may combine the documented procedures for corrective and preventive action if you wish
4.2.3 f	Clarification that the external documents referred to are those needed for use in the QMS
4.2.4	This clause has been significantly reduced in length but the requirement remains unchanged
5.1 a	The word statutory has again been added
5.5.2	The requirement that the management representative needs to be a member of the organisation's management has been added
6.2	Change in title but keeps same words (change in their order) Where the current version mentions '... affecting product quality', it now states '... affecting conformity to product requirements'. 6.2.2 b) now states that 'where applicable' training needs to be provided to achieve the 'necessary competence' 6.2.2 c) now requires that the achievement of competence has been ensured rather than checking the effectiveness of training
6.3	c) now includes information systems
6.4	A note has been added to clarify what work environment includes and gives some examples such as noise, temperature, humidity
7.1 c	The word measurement has been added
7.2.1	a) slightly re-worded c) the word 'related' has changed to 'applicable' d) the statement about additional requirements determined by the organisation becomes 'considered necessary' by the organisation A note has been added to explain what the phrase 'post delivery activities' may include i.e. warranty provisions, etc
7.3.1	A note has been added to explain that design review, verification and validation are separate activities though they may be performed separately or in any combination e.g. verification and validation may be performed together
7.3.2	'These' inputs becomes 'the' inputs (last para)
7.3.3	The word 'provided' has been removed and the phrase 'suitable for' replaces 'that enables' b) the word 'for' (service provision) has been removed A note has been added regarding the inclusion of 'preservation of product'
7.5.3	An added requirement to clarify that inspection and test status must be identified 'throughout product realisation' Slight re-wording of record requirement under traceability
7.5.4	Re-wording of the requirement to inform the customer if there is a problem and keep records The phrase 'and personal data' has been added to the note about intellectual property
7.5.5	Re-wording of 'conformity of' to 'in order to maintain conformity to requirements' 'Where appropriate, this' has changed to 'as applicable'
7.6	The word 'devices' in the title has been changed to 'equipment' The reference to 7.1 has been removed c) 'be identified to enable the' has been changed to 'have identification to enable their' Note 1 has been amended to remove the reference to ISO 10012-2 and has been replaced by a Note 3 to explain about the verification and configuration management of computer software (where it is used to monitor and measure)
8.2.1	A Note has been added to provide some ideas as to how customer satisfaction can be measured
8.2.2	The requirement for a documented procedure has been re-worded but remains unchanged A requirement for records of the audits and their results has been added A requirement for management responsible for the area audited to ensure that 'necessary corrections and corrective actions' has been added The Note that makes reference to the fact that ISO 10011 has changed and now refers to ISO 19011
8.2.3	The phrase 'to ensure conformity of the product' has been removed A Note has been added to explain that the organisation should consider the type of monitoring and measuring of processes and the extent to which they affect quality and the QMS
8.2.4	The requirement to 'maintain evidence of conformity with acceptance criteria' has moved but

	is still a requirement Clarification of the fact that product release/service delivery is 'to the customer' has been added
8.3	The requirement for a documented procedure has been re-worded but remains unchanged The phrase 'where applicable' has been added to the methods for dealing with nonconforming product The requirement to deal with nonconforming product discovered after delivery has been moved to be bullet point d) but is unchanged The records requirement has moved but is unchanged

Summary

As can be seen from the list of changes, there are very few of any consequence and most organisations will have little problem adapting their system to satisfy these changes.