

ISO 9001:2000 to ISO 9001:2008 Changes

With Suggested Impacts to Organisations

Introduction

The update process for ISO 9001 is now complete in that the standard was issued on the 14th November 2008. This document has been produced for people who do not yet have access to the standard to see what the proposed changes are and also added is the likely impact of these changes to the 'average organisation'.

It is difficult to know exactly what the impact will be on different organisations as the majority have different quality management systems so a 'typical' system has been considered when making the judgements. If your system is one in which you have copied/quoted the words of the 2000 version of ISO 9001 e.g. in your quality manual, you will have a little more work to do. You may also review that decision when updating it to the 2008 version!

It is important for each organisation to review their own system when considering the changes but I trust that these thoughts may be of some benefit.

Overall, as you will see, there is not much for most organisations to do in order to bring their systems up to the 2008 version, which was one of the intentions when reviewing and amending the standard. It was always intended that ISO9001:2008 would be a minor revision from ISO9001:2000 and so it has turned out to be.

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| 9001 Clause No. | Change | Suggested Action |
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| 1.1 1.2 | The word statutory has been added. Clarification in Note 1 about what the 'product' is. Note 2 added to explain that statutory and regulatory may be expressed as legal requirements. | The changes are unlikely to affect most organizations but it is suggested (if not done already) that all organisations should establish which statutory and regulatory requirements are applicable to the product they provide. |
| 2 | The paragraph on normative references has been re-worded and the updated version of ISO 9000 (2005) is now referenced. | No action required. |
| 3 | The description regarding suppliers, organisation and customers has been removed. | No action required. |
| 4.1 | a) Identify replaced with determine. e) where applicable added. | No action required. |
| 4.1 | Further explanation provided regarding the control necessary over 'outsourced processes'. | Probably no action required but it may be worth ensuring that your organisation fully addresses this requirement as its profile will be raised and is more likely to be checked more thoroughly by auditors. |
| 4.1 | Note 1 amended to include 'analysis and improvement'. Notes 2 & 3 added to provide further clarification about outsourced processes. | Check that the organisation includes processes for analysis and improvement. See point above regarding outsourced processes. |
| 4.2.1 | Bullet e) has been removed and the requirement for records placed in bullets c) & d). | No action required. |
| 4.2.1 | Note 1 modified to explain that you do not have to have 1 procedure for each clause (e.g. corrective action), it may be combined with another (e.g. preventive action) and that a clause may be addressed in more than 1 procedure e.g. nonconforming product may be addressed in the department where it happens rather than in just 1 procedure. | No immediate action required but it may be worth considering this as part of the improvement process. |
| 4.2.3 | f) Clarification added that external documents requiring control are only those necessary for use in the QMS. | Probably no action required. |
| 4.2.4 | Clause re-worded but no change in content or intent. | No action required. |
| 5.5.2 | Included is the requirement for the management representative to be a member of the organisation's management – not just management. | No action required. |
| 6.2.1 | Slightly re-worded but no change to the intent. | No action required. |
| 6.2.2 | Title changed around but still the same. | Possibly change procedure name and references in the quality manual. |
| 6.2.2 | a) 'product quality' changed to 'conformity to product requirements' b) bullet point amended to state that 'where applicable' it is required to provide training or take action to 'achieve the necessary competence' | No action required. |
| 6.3 | c) another example of supporting services has been added (information systems) | No action required. |
| 6.4 | A note has been added to give examples of the type of work environment which could affect product conformity. | No action required. |

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| 7.1 | b) slight rewording c) The word 'measurement' has been added | No action required. Verify that the organisation considers measurement as part of the planning process. |
| 7.2.1 | c) slight change in wording that statutory and regulatory requirements are those 'applicable' to the product rather than those 'related' to the product. d) the additional requirements are now 'those considered necessary' rather than 'those determined'. Note added to provide some examples of the 'post delivery activities' referred to in a) | No action required. No action required. Check that the current process addresses this requirement. |
| 7.3.1 | Note added to explain that review, verification and validation can be done separately or combined. | No action required. |
| 7.3.2 | 'These' inputs changed to 'the' inputs | No action required. |
| 7.3.3 | Slight rewording but no change in the intent. Note added | No action required. |
| 7.5.1 | d) the word 'devices' has been changed to 'equipment' (see 7.6) f) the word 'product' has been inserted to clarify that the requirement relates to product release. | No action required. |
| 7.5.2 | Slight rewording but no change in the intent. | No action required. |
| 7.5.3 | Para 2 now clarifies that product status must be identified 'throughout product realisation'. The requirement to keep records in para 3 has been reworded but not changed. | No action required. |
| 7.5.4 | Clause reworded but no change in content or intent. 'Personal data' added to the note. | Check that personal data has been considered if it is applicable to your organisation. |
| 7.5.5 | Slight rewording but no change to content. Clarification that the methods of providing preservation are 'as applicable'. | No action required. |
| 7.6 | Title and para 1 changed in that the word 'devices' has become 'equipment'. | Unlikely to affect most organisations but check that you have included process equipment such as ovens, etc. in the calibration schedule. |
| 7.6 | a) 'or both' has been added after 'calibrated or verified' c) reworded but no change in content or intent | No action required. |
| 7.6 | Requirements to keep records is now a separate sentence. | No action required. |
| 7.6 | Note referring to ISO 10012 has been removed and a new Note regarding verification of computer software and configuration management has been added. | Unlikely to require any action. |
| 8.1 | a) conformity 'of the product' has been changed to 'to product requirements'. | No action required. |
| 8.2.1 | Note added to provide examples of how information on customer satisfaction can be gathered. | Review current method for effectiveness and consider some of the alternatives if required. |

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| 8.2.2 | The old para 3 has been split into 2 paragraphs to emphasise that a documented procedure is required and records of audits must be maintained but the requirement is still the same. | Probably no action required. |
| 8.2.2 | Para 4 now states that 'any necessary corrections and corrective actions' must be taken rather than just 'actions'. | Check that your internal audit procedure includes this requirement and that internal auditors understand the difference between 'correction' and 'corrective' actions. |
| 8.2.2 | The reference to ISO 10011 has been replaced with ISO 19011. | No action required – unless your procedure still quotes ISO 10011. |
| 8.2.3 | The words 'to ensure conformity of the product' have been deleted. | Unlikely to require any action. |
| 8.2.3 | A note has been added to clarify which type of monitoring and measuring methods may be considered to satisfy this requirement. | Unlikely to require any action but review existing methods for effectiveness and if required, consider alternatives methods. |
| 8.2.4 | The requirement that 'evidence of conformity with the acceptance criteria shall be maintained' has been moved from para 2 into para 1. | No action required. |
| 8.2.4 | Para 2 - 'for delivery to the customer' has been added to the requirement to keep records of who authorised release of product. Para 3 – slight rewording but no change to content or intent. | Unlikely to require any action. No action required. |
| 8.3 | Rewording of para 1 but no change to content or intent. 'Where applicable' has been added to the start of para 2. | No action required. |
| 8.3 | Paras 3 & 4 have been re-organised but the content is unchanged. Para 5 has become bullet point d) and reworded but the intent is the same. | No action required – unless your procedure for nonconforming product quotes the ISO 9001:2000 words. |
| 8.4 | b) now references 8.2.4 rather than 7.2.1. c) references 8.2.3 and 8.2.4 d) references 7.4 | No action required. |
| 8.5.2 | Para 1 now states the 'causes' rather than 'cause' of nonconformity. | No action required. |
| 8.5.2 | f) requires a review of 'the effectiveness' of corrective action taken' rather than just the 'corrective action taken'. | May require clarification in your procedure and for people involved in these activities that the review must ensure that the action taken has worked and removed the nonconformity, not just that it has been done. |
| 8.5.3 | e) requires a review of 'the effectiveness' of preventive action taken' rather than just the 'preventive action taken' | May require clarification in your procedure and for people involved in these activities that the review must ensure that the action taken has worked and removed the potential for nonconformity, not just that it has been done. |