

Dear Madam and Sir,

The revised ISO 9001:2008 was published by the International Organization for Standardization (ISO) on November 14th, 2008. In this newsletter we would like to inform you about the changes and possible implications regarding your existing management system and your certificate.

ISO 9001:2008 delivers no additional requirements compared to ISO 9001:2000. Existing requirements have been reworded in a more precise manner. In a release dated 2008-08-20 ISO states that "ISO 9001:2008 does not contain any new requirement".

In general, some clauses of the revised ISO 9001:2008 have been tightened whilst others have been softened. Many of the changes are limited to amended phrases or even wording (e.g. "devices" being replaced by "equipment"), in other cases paragraphs were re-ordered but with no effect onto existing management systems. Changes compared against the recently published FDIS are of very minor importance.

However, there are changes regarding the process of certification:

- New and renewed certificates are to be issued according to ISO 9001:2008 after 12 months following publication of ISO 9001:2008
- All existing certificates according to ISO 9001:2000 will become invalid after 24 months following publication of ISO 9001:2008
- Transfer of existing certificates requires a surveillance or renewal audit according to ISO 9001:2008

The more important changes can be summarised in the following categories:

Legal requirements (product-related)

- It is now defined as statutory and regulatory requirements
- Affects mainly 0.1, 1.1, 1.2, 7.2.1
- Should have no effect on customers of GLC as we have always taken this point into consideration during our audits

Product requirements

- Now also includes desired outcome
- Focuses even more strictly on how those requirements are being met throughout the whole process landscape of the organisation
- Affects mainly 0.2, 1.1, 6.2.1, 6.2.2, 8.1, 8.2.4 but the implications will vary very much between industries

Processes descriptions

- Now to be determined (rather than identified)
- Affects mainly 0.2, 4.1
- May require a complete check of your process landscape against your documentation
- Also, measuring of processes is now limited to those processes where applicable (4.1)
- The different phases during design & development may now be performed either in sequence or combined – as it best fits the organisation (7.3)
- When dealing with non-conforming products, the existing clause is now compulsory only “where applicable” (8.3)

System documentation

- Softening in that respect that it now very much depends on what the organisation defines as necessary for planning and operation of the management system
- Mainly affects 4.2.3, 7.2.1, 7.3.3, 7.5.3
- Should be analysed individually

Outsourcing of processes

- More precise and extended description including rewording of definition
- Control of processes shall be defined within QMS
- Explanatory note regarding the control of outsourced processes
- NEW: linking of outsourcing with purchasing
- Affects mainly 4.1 and 7.4
- Obviously the effects of this revision will depend on how many of the processes affected have actually been outsourced and what control regime has already been applied

Records

- Records are now sometimes directly linked with documents, i.e. with respect to documentation and internal audits (i.e. records of internal audits now shall include records of audits and their results)
- Affects mainly 4.2.1 and 8.2.2
- If not already the case, compliance can be achieved by keeping all records of internal audits including checklists, protocols, reports, schedules, plans etc.

Another important issue is that the ISO 9001:2008 now requires the management system representative to be member of organisation's management. External QMRs are no longer permitted, however, delegation of tasks is still an option. The ISO 9001:2008 aims at making quality a top management issue which needs to be represented by a member of the top management.

ISO 9001:2008 also contains an extended explanatory note for the evaluation of client satisfaction: methods mentioned include particularly customer data on delivered product quality, user opinion surveys, lost business analysis etc. This note definitely is a move away from the sending out of questionnaires (which reportedly have achieved very rarely satisfactory return rates).

We will inform you in another newsletter as soon as the ISO 9001:2008 has been published. Please visit our homepage for up-to-date information on GLC.