

Information and Comments about: “ISO 9001:2008”

Stand: 15th December 2008

The transition from the “old“ to the “new“ standard

ISO 9001:2008 was published on 15th November 2008. At 15th November 2009 – one year after the publication of the new standard – all accredited certificates must be issued as per this new standard. This applies to both initial and re-certification. At 15th November 2010 – two years after the publication of ISO 9001:2008 – every existing certification as per ISO 9001:2000 will become invalid. This applies to certificates with imprinted expiring dates after this deadline, too. Because of these, it is important to observe the pertinent deadlines.

Our recommendations for an easy and smooth transition

We recommend different approaches to the transition depending on the certificate's period of validity. The deadline for the transition to the new standard is 15th November 2010.

- If your certificate's period of validity expires before 15th November 2010, we recommend an upgrade to the new standard within the scope of a re-certification audit
- If your certificate's period of validity expires on or after 15th November 2010, we recommend an upgrade within the scope of the next surveillance audit

Regardless of when the transition is effected, no additional costs will arise for our clients.

No additional auditor time will be necessary for the surveillance audit.

The conditions for the issue of certificates are the same as for regular recertification audits, i.e. one original and two copies are free of charge.

What's new?

According to an official notification called the Joint IAF-ISO communiqué, the new ISO standard does not include any new requirements. With explanations and changes of text, it was tried to improve the clarity of the existing requirements. Furthermore it aims at improving consistency with ISO 14001:2004.

Presently there is no official publication of comments on the changes which try to express the intention of the ISO 9001:2000 more clearly. On basis of the present discussions, the following points can require changes in management system.

Chapter	Extract from ISO 9001:2008	Comment
0.1	<p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.</p>	<p>Meet requirements applicable to the product and the organization's own requirements => customers, statutory and regulatory requirements are only relevant as far as they are applicable to the product, other requirements from these parties are only relevant if they are part of the organizations own requirements.</p>
4.1	<p>The organization shall ... a) determine the processes needed for the quality ... e) monitor, measure (where applicable), and analyse these processes,</p>	<p>All processes need to be monitored and analysed. Its not necessary to measure each process (measurement is needed only where applicable)</p>
4.1	<p>Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.</p> <p>NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.</p>	<p>Outsourced processes have to be focussed on in the audit. Depending on the organization's activities for monitoring the outsourced processes, the auditor has to decide how often and how long he needs to audit the outsourced processes at the site of the external party.</p>
4.2.1	<p>The quality management system documentation shall include ... d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.</p>	<p>Documentation shall include documented procedures, documents and records required by the ISO 9000 or determined by the organization to be necessary. It is not the job of the auditor to decide which documents are needed by the company, he has to decide which information is needed.</p>

Chapter	Extract from ISO 9001:2008	Comment
5.2.2	<p>Top management shall appoint a member of the organization's management who, ...</p> <p>NOTE The responsibility of a management representative can include liaising with external parties on matters relating to the quality management system.</p>	<p>The management representative has to be a member of the organization's management, not only of management => External parties cannot be the official management representative (the tasks can also be delegated), even if most of his tasks and responsibilities are outsourced to external parties (see the note for chapter 5.5.2).</p>
8.2.1	<p>...</p> <p>NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.</p>	<p>The new note gives examples for monitoring customer perception. => If there is enough other information, interviewing customers is not necessary.</p>
8.2.2	<p>8.2.2 Internal Audits</p> <p>...</p> <p>Records of the audits and their results shall be maintained (see 4.2.4)</p> <p>...</p>	<p>The organization has to maintain records of internal audits. Only documenting the results is not sufficient.</p>
8.5.2	<p>8.5.2 Corrective action</p> <p>...</p> <p>A documented procedure shall be established to define requirements for</p> <p>...</p> <p>f) reviewing the effectiveness of the corrective action taken.</p>	<p>The documented procedure for corrective actions shall contain a description of how to review the effectiveness of the corrective actions.</p>
8.5.3	<p>8.5.3 Preventive action</p> <p>A documented procedure shall be established to define requirements for</p> <p>...</p> <p>e) reviewing the effectiveness of the preventive action taken.</p> <p>...</p>	<p>The documented procedure for preventive actions shall contain a description of how to review the effectiveness of the preventive actions.</p>