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ISO 9000:2008 – what's changed from ISO 9001:2000

1. Introduction

The ISO 9000 standards are a set of international management standards and guidelines. First published in 1987, the last major update was in 2000 when the emphasis changed from documenting processes and record keeping to one of customer satisfaction and business improvement and excellence.

This was a major learning experience for many in business and also for many quality auditors and consultants.

In November 2008 the standards were updated again but the changes are mainly to clarify a few points and also to make it easier to translate the standards into languages other than English and French without the meaning becoming obscured. There are however some changes that all users should be aware of; see below.

2. Effect of the Changes

As before, the revised standard is intended to guide organisations to base their OMS (Organisational Management System) on the way that they really operate. To obtain ISO 9001:2008 accredited registration organisations have to understand their core processes, for example, how raw materials become finished goods. This reflects good modern management practice but there are still organisations that paste the words of the standard into word processing documents and then try to convert them into their operating procedures, which never work!

3. Effect on Organisations with Accredited Registration

Until your registration body has been accredited to provide registrations to ISO 9001:2008 they will not be able to upgrade your registration to the new standard. In the UK to be accredited they will have to prove to UKAS, the United Kingdom Accreditation Service, that their auditors and review staff have been trained to the new standard. At the time of writing the likely timescales are not known but, as the changes are so small this is likely to be within two years of the standard being approved, i.e. before the end of 2010.

4. Overview of the Changes

There are still four primary standards:

- ISO 9000:2005 Quality Management Systems Fundamentals and Vocabulary
- ISO 9001:2008 Quality Management Systems - Requirements
- ISO 9004:2000 Quality Management Systems Guidance for Performance Improvement
- ISO 19011:2002 Guidelines on Quality and Environmental Auditing

ISO 9001 addresses the OMS requirements for an organisation to meet its customers' needs. ISO 9004 goes beyond ISO 9001 towards business excellence and as the new and earlier version of ISO 9001 are so similar this is still applicable.

ISO 9001 uses the common vocabulary defined in ISO 9000:2005, which also describes the underlying fundamentals.

The new changes are described below in detail:

The clause numbers for both issues of ISO 9001 are identical; there are however, some new sub-clauses, prefixed with lower case letters and some new guidance notes.

General Requirements – Clause 4.1

Many organisations outsource parts of their business processes but this revised section emphasises that complying with all regulatory, mandatory and customer requirements it is still **the organisation's responsibility!** This is the opposite of the situation with product liability legislation in the EU and in many other countries, where blame for a problem is passed up the chain of supply to the organisation where the problem originated.

General – Clause 4.2.1

It is made clear that the standard does not specify how documented procedures are arranged. One procedure may address more than one clause of the standard and alternatively; more than one procedure may be needed to cover just one clause of the standard. This is only stating common sense.

Control of Documents – Clause 4.2.3 f)

Many organisations use documents from outside sources as part of their OMS. They are now required to identify this documentation and ensure it is distributed and maintained to the same degree as their own documentation.

This will particularly affect businesses that perform a large amount of subcontract work, for example, sub-contract assembly. They will have to maintain processes to ensure that the correct issue drawings and documents are in use for each job. An efficient business would be doing this anyway.

Management Representative – Clause 5.5.2

This will probably have more effect than any of the other changes.

Currently most organisations have a 'Quality Manager' who is not a member of the management team. While the day to day running of the quality processes may still be delegated to a 'Quality Manager' as before, a member of the management team must take ultimate responsibility for quality. An auditor will expect this to be shown in the company structure and the management team member to be fully aware of the quality issues in the organisation.

Human Resources – General – Clause 6.2.1

Staff competence is the key to the performance of any organisation and the quality of its products and services. The need to ensure that its staff are competent to do their tasks has been strengthened to include tasks that do not directly affect the quality of the product or service. Again, an efficient organisation would already be doing this.

Infrastructure – Clause 6.3 c)

'Information systems' are now specifically included as part of the organisations' infrastructure.

Work Environment – Clause 6.4

Physical factors that affect the work environment and through this product and service quality, such as weather, lighting, sound and temperature are specifically mentioned.

Customer Related Processes – Clause 7.2.1 a)

As above for the work environment, specific examples of post delivery activities are mentioned such as warranty and contractual support and recycling.

Design & Development Planning – Clause 7.3.1

Additional guidance has been added and planning can be done as one activity or separately, whichever is most effective. Again this reflects common sense.

Design & Development Outputs – Clause 7.3.3

A note has been added that service provision can include details of product preservation.

Control of Monitoring and Measuring Equipment – Clause 7.6

The clause has been re-titled from 'Control of Monitoring and Measuring Devices'.

Where software is used specific mention is made of configuration control and verification.

Customer Satisfaction – Clause 8.2.1

Examples of where customer satisfaction can be measured have been added.

Internal Audits – Clause 8.2.2

The standard now states that records of internal audits must be maintained. This will already be the case for organisations with accredited registration to ISO 9001, as the external auditors review the internal audit reports.

Monitoring and Measurement of Processes – Clause 8.2.3

Additional guidance has been added that for each monitoring and measuring process the impact on the quality of the product and its effectiveness within OMS must be assessed.

Monitoring and Measurement of Product – Clause 8.2.4

The organisation must maintain records of who is responsible for signing off the product for delivery.

5. The Eight Quality Management Principles of ISO 9001:2008

The new revision of ISO 9001 retains the eight quality management principles from the previous version:

- Customer focused organisation
- Leadership
- Involvement of people
- Process approach
- System approach to management

- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship

6. ISO 9004:2000

ISO 9004:2000 represents best business practice and has much in common with Investors in People, the European Quality Model and with various other Business Excellence Models that have been used successfully by some of the world's most profitable companies.

The new revision of ISO 9004 has been published for comment. It will no longer be arranged to be compatible with the clauses of ISO 9001 and instead will be arranged around the eight Quality Management Principles. It will also have a new title, 'Managing for the Sustained Success of an Organisation – A Quality Management Approach'. A revised self-assessment tool will be included that is based on system maturity.

Organisations cannot be registered to ISO 9004.

7. In Conclusion

The introduction of ISO 9000:2008 will not have a major effect on organisations registered to ISO 9001:2000 but there are changes that must be implemented to obtain or retain accredited certification.

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