



NSAI

National Standards Authority of Ireland
Údarás Um Chaighdeáin Náisiúnta na hÉireann

ISO 9001:2008 Transition Policy

Issued: January 2009

ISO 9001:2008 was officially published on November 15, 2008. The intent of the revision (officially called an “amendment”) was to limit any changes to those where there were clear benefits to users and where the potential impact was relatively low. ISO list these “high benefit” areas as:

- Removing ambiguity in the requirements
- Providing clearer text
- Improving compatibility with ISO 14001
- Improving the ability to translate to other user languages
- Incorporating interpretations which were formally posted on the TC176 website

Key Changes

NSAI have identified three key issues which have to be verified before a certificate can be issued to ISO 9001:2008. This verification will take place during your routine on site audit but will not require any additional time. These three issues are:

4.1: Outsourcing

No change in requirements but the new notes makes the requirements clearer.

5.5.2: Management Representative

Now has to be a member of the organization’s management. If a consultant is being used to fill this role, the person has to be integrated into the organization so that he/she has adequately defined authority and responsibility.

7.5.4: Customer Property

A note has been extended to specifically mention personal data. This implies that the organization must safeguard any personal data (e.g. bank details, credit card information etc.)

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Transition Plan

NSAI consider these changes to be very minor in nature and we will begin officially auditing to ISO 9001:2008 on February 1, 2009. ISO (International Organization for Standards) and the IAF (International Accreditation Forum) have agreed on the following implementation plan to ensure a smooth migration of accredited certifications to ISO 9001:2008:

Effective November 15, 2009, all certificates issued (either new or re-certification) shall be to ISO 9001:2008.

Effective November 15, 2010, any certificates issued to ISO 9001:2000 shall be invalid.

Key Questions and Answers

Q: What if NSAI raise a finding against ISO 9001:2008?

A: Given the very minor changes to the standard, the finding(s) will need to be closed as any other deviation identified during the audit.

Q: When does my current ISO 9001:2000 certificate expire?

A: Either on the expiry date stated or, if this is after 15 November 2010, it will cease to be valid on 15 November 2010.

Q: Where can I find out more about the changes?

A: We have provided a brief summary of the changes below and utilize the link below to purchase a copy of the standard.

<http://www.n Sai.ie>

GUIDE TO CHANGES IN ISO 9001:2008

Disclaimer: This list is not exhaustive

CLAUSE	CHANGE
0.1	General: Refers to the organization's business environment
0.2	Process Approach: Text now refers to the importance of processes being capable of achieving desired outputs
0.3	Relationship with ISO 9004: No longer produced as "consistent pair"
1.1	Scope: Clarifies the use of the word "product"
4.1	General Requirements: (e) Refers to the fact that measurement may not be appropriate to all processes but monitoring is required. Notes added referring to Outsourcing
4.2.1	Documentation: QMS documentation now includes "records". Documents required by the standard may be combined or covered in multiple documents.
4.2.3	Document Control: "External Documents" only applies to those impacting on the planning and operation of the QMS



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5.5.2	Management representative: Now has to be a member of the organization's management
6.2.1	Human Resources: Competence requirements does not only cover those directly working with the product but covers those indirectly involved (e.g. purchasing, IT, etc.)
6.3	Infrastructure: Recognizes the importance of information technology
7.1	Planning of Product Realization: Planning of product realization now includes measurement (where appropriate)
7.2.1	Customer Related Processes: Clarifies that "post-delivery" activities may include warranty, maintenance, recycling, final disposal or other legal or contractual obligations
7.3.1	Design and Development Planning: Note explains that design review, verification and validation have distinct purposes
7.3.3	Design and Development Outputs: Note explains that design outputs may include those associate with the product such as packaging (product preservation)
7.5.3	Identification and Traceability: Now notes that identification may be needed throughout the production process and not just on final product.
7.5.4	Customer Property: Now notes that personal data has to be safeguarded
7.6	Control of Monitoring and Measuring Equipment: "Measuring devices" changed to "measuring equipment". Note added regarding computer software.
8.2.1	Customer Satisfaction: Note added explaining the wide range of inputs which might be considered when monitoring customer satisfaction
8.2.2	Internal Audit: Both correction and corrective actions must now be addressed
8.2.3	Monitoring / Measurement of Process: Whenever QMS processes do not achieve planned results, the organization must evaluate the need to make corrections and/or corrective action regardless of direct impact on product. A note has been added to clarify that the organization must consider both the direct impact on the product and the effectiveness of the QMS.
8.5.2 (f) 8.5.3 (f)	Corrective and Preventive Action: "Reviewing ... action taken" changed to "reviewing the effectiveness of ... action taken"
General	Editorial Changes: Many minor editorial changes have been added such as: <ul style="list-style-type: none"> • Referring consistently to statutory and regulatory requirements • Moving wording around with the same ultimate meaning • Changing "and/or" to "or" • "Cause" changed to "causes" etc.