

# “Speaking Out”

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## STANDARDS

### *ISO 9001:2008 Is Just Around The Corner*

*By John Novak*

The ISO 9001:2000 standard is about to be amended. The amended standard will be called ISO 9001:2008, and is expected to be released before the end of 2008. According to technical experts on TC 176, an amendment addresses known issues but does not create new or delete existing requirements. This was confirmed in a joint communiqué from the International Accreditation Forum (IAF) (<http://www.iaf.nu>) and the International Organization for Standardization (ISO) (<http://www.iso.org/iso/home.htm>), which stated, “ISO 9001:2008 does not contain any new requirements”.

Since the requirements have not changed, the issues that needed to be addressed were handled in the following ways:

1. Restructuring clauses in order to improve clarity.
2. Notes were added, changed, or deleted in order to clarify the requirements without having to change the text in the actual clause.

In order to easily identify all of the changes, Annex B is included which details all of the changes on a clause by clause basis.

Included in the same joint communiqué mentioned above, was the announcement of the following implementation plan which is intended to ensure a smooth transition from ISO 9001:2000 to ISO 9001:2008:

1. Certification to ISO 9001:2008 cannot be completed until the new standard is formally published.
2. ISO 9001:2000 certifications will cease 12 months after publication of ISO 9001:2008.
3. Organizations with ISO 9001:2000 certifications will have 24 months to complete the transition to ISO 9001:2008.

Some of the clarifications include:

- Statutory requirements are treated like other regulatory or requirements and include the supplier’s requirements.

- A purchased process is treated just like a purchased product.
- A single document can include the requirements of two procedures.
- The management representative must be a member of the management.
- A requirement to ensure that trainings are suitable for the product in advance and not to check if the training was effective after it was taken.
- Information system is now officially considered as a substructure.
- Parameters such as humidity, noise and temperatures, concerning the employees' health are considered as working environment.
- Measuring is considered as one of the activities of product realization.
- The product must be identifying not only on the shelves but also throughout the realization process.
- The management is now responsible for preventive and corrective actions regarding nonconformities that were discovered during audit.
- The organization should determine the type of the monitoring and measuring according to the processes and how will this affect the quality management system.

*KAVON International, Inc. is a business consultancy that helps clients create **Value** in order to attain and sustain a **Competitive Advantage** in the markets they serve. If your company is seeking registration or compliance to any of the Quality Management System standards such as ISO 9001, ISO/TS 16949, AS9100, ISO 17025, ISO 14001, or ISO 13485, or wants to establish a continual improvement program using Lean Six Sigma methodologies, give us a call and let one of our *Trusted Advisors* help you with implementation and training.*