

**Identify the Differences between  
ISO9001:2000 and ISO 9001:2008**

審視  
**ISO9001:2000 與 ISO9001:2008**  
版本的異同

5 January 2009

WHEN YOU NEED TO BE SURE

**SGS ISO 9000 SERIES**

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 2

**SGS ISO 9000 SERIES – ISO 9001**

- 1982 - Work started
- 1987 - First publication – ISO 9001:1987
- 1994 - Second edition – ISO 9001:1994
- 2000 – Third edition – ISO 9001:2000
- 2008 – Fourth edition – ISO 9001:2008 (Latest)

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 3

**SGS ISO 9000 Family amendment history**

Definition	Specification	Guidance
ISO8042:1986	ISO9001/2/3:1987	ISO9004:1987
	ISO9001/2/3:1994	ISO9004:1994
ISO9000:2000	ISO9001:2000	ISO9004:2000
ISO9000:2005	ISO9001:2008	ISO9004:2009

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 4

**SGS TC176 Key Messages for ISO 9001 Amendment**

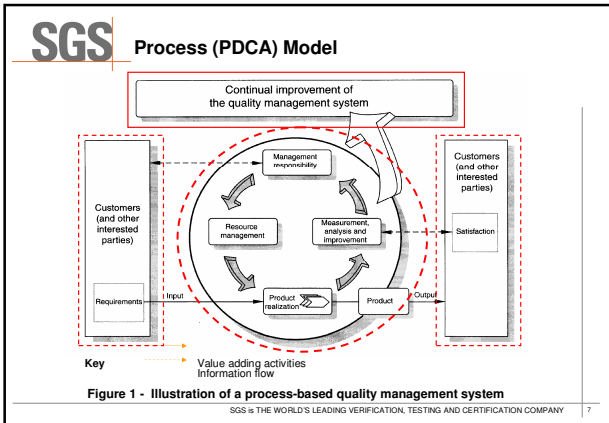
- ... project should be undertaken for a **limited amendment** to ISO 9001:2000
- in order to satisfy user needs, the amended standard shall **remain generic** and be applicable to all sizes and types of organization operating in any sector
- ... the impact on the users shall be limited, and changes will only be introduced where there are **clear benefits to users**.
- The current scope and purpose of the standard, the title and the field of application shall be **unchanged** from ISO 9001:2000
- Certification to ISO9001:2008 is **not an "upgrade"**, organization certified to ISO9001:2000 should be the same status

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 5

**SGS TC176 Key Messages for ISO 9001 Amendment**

- ...enhanced **compatibility** with ISO14001:2004 (in turns, OHSAS18001:2007)
- Improved **clarity and easy for use**, changes made only there are benefits
- Changes confined to **minimized impact** on users
- The process model as shown in ISO 9001:2000, Figure 1, shall remain **unchanged**.

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 6



**Highlighted Differences  
between ISO9001:2000 and  
ISO9001:2008**

**SGS**  
WHEN YOU NEED TO BE SURE

**SGS ISO 9001 : 2008 Amendment Highlights**

- This session consists of highlighted changes in ISO9001:2008, but not an in-depth comprehensive explanation of each clauses
- Details of the changes between ISO9001:2000 and ISO9001:2008 are given in Annex B Table B.1 of the standard.

SGS IS THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 9

**SGS ISO 9001 : 2008 Amendment Highlights**

- 0.1 General
- **Highlighted changes:** ISO9001:2008 adds "organization environment", "changes", "risk" to factors that influence the design and implementation of QMS.

- The design and implementation of an organization's quality management system is influenced by
  - a) **its organizational environment, change in that environment, and the risks associated with that environment [Added]**
  - .....
- This International Standard can be used by internal and external parties, ..... the organization's ability to meet customer, **statutory [Added]** and regulatory requirements **applicable to the product [Added]**, and the organization's own requirements.

SGS IS THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 10

**SGS ISO 9001 : 2008 Amendment Highlights**

- 0.2 Process approach
- **Highlighted changes:** Definition of process approach is clarified by adding "to produce the desired outcome"

- The application of a system within an organization, together with the identification and interactions of these processes, and their management **to produce the desired outcome [Added]**, can be referred to as the "process approach". (add for clarification)

SGS IS THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 11

**SGS ISO 9001 : 2008 Amendment Highlights**


- 1 Scope
- **Highlighted changes:** ISO9001:2008 expands the use of "regulatory" to "statutory and regulatory" and may be expressed as "legal" requirements.

- 1.1 General
- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable **statutory [Added]** and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable **statutory [Added]** and regulatory requirements.
- NOTE 1 In this International Standard, the term "product" applies to the product intended for, or required by, a customer or the product realization processes. This applies to any **intended output resulting from [Added]** product realization processes, including purchasing.
- NOTE 2 **Statutory and regulatory requirements may be expressed as legal requirements. [Added]**

SGS IS THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 12

## SGS ISO 9001 : 2008 Amendment Highlights

- 2 Normative reference
  - Only **re-phrasing** of sentence. The text has been significantly reduced.
  - **Updating** version of ISO 9000 to 2005 version.
- 3 Terms and definitions
  - Only **deleting** explanation of supply chain terms. "Organisation" replaced "supplier"; "Supplier" replaced "subcontractor". (i.e. Remark to explain the difference between terminologies from ISO9001:1994 and ISO9001:2000)




SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 13

## SGS ISO 9001 : 2008 Amendment Highlights

- 4 Quality Management System
- 4.1 General requirements
- **Highlighted changes:** Product is now required to meet customer and applicable statutory and regulatory requirements.

"Identify" (the processes) was replaced by "determine"

- a) **determine [is amended from "identify"]** the processes needed for the quality management system and their application throughout the organization (see 1.2) ...
- e) monitor, measure **(where applicable) [Added]**, and analyse these processes, and ...
- Where an organization chooses to outsource any process that affects product conformity **is [is amended from with]** requirements, the organization shall ensure control over such processes. **The type and extent of control [Re-wording]** to be applied to these outsourced processes shall be defined within the quality management system.




SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 14

## SGS ISO 9001 : 2008 Amendment Highlights

- 4.1 General requirements
- New notes added on what is considered an outsourced process and identifies factors influencing the control of outsourced process.


- NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement, **analysts and improvement [Added]**.
- NOTE 2 **An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization. [Added]**
- 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 nature of control to be applied to the outsourced process may 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 extent to which the control for the process is shared;**
  - c) **the capability of achieving the necessary control through the application of clause 7.4. [Added]**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 15

## SGS ISO 9001 : 2008 Amendment Highlights


- 4.2 Documentation requirements
- **Highlighted Changes:** Clarifications include a single document may now address the requirements of one or more procedures and that a documented procedure may be covered by more than one document.
- Documents of external origin determined by the organisation to be necessary for the planning and operation of the QMS are to be identified and their distribution controlled.



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 16

## SGS ISO 9001 : 2008 Amendment Highlights


- 4.2 Documentation requirements
- 4.2.1 General
  - c) documented procedures **and records [Added]** required by this International Standard, and
  - d) documents, **including records [Added], determined [is amended from needed]** by the organization to be necessary to ensure the effective planning, operation and control of its processes.
  - NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. **A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. [Added]**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 17

## SGS ISO 9001 : 2008 Amendment Highlights


- 4.2 Documentation requirements
- 4.2.3 Control of documents
  - f) to ensure that documents of external origin **determined by the organization to be necessary for the planning and operation of the quality management system [Added]** are identified and their distribution controlled, and
- 4.2.4 Control of records
  - (Rewritten with editorial change for alignment with ISO14001 only)
  - **Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.**
  - **The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.**
  - **Records shall remain legible, readily identifiable and retrievable.**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 18

**SGS ISO 9001 : 2008 Amendment Highlights**

- 5.5 Responsibility, authority and communication
- Highlighted Changes:** Reinforces the principle that a member of the organization's management shall be responsible for all aspects of the QMS.
  - 5.5.2 Top management shall appoint a **member of the organization's management (Added)** who, irrespective of other responsibilities, shall have responsibility and authority that includes,....




SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 19

**SGS ISO 9001 : 2008 Amendment Highlights**

- 6.2 Human resources
- Highlighted changes:** Expands the responsibility of those overseeing product quality to include that those performing work affecting product requirements are competent. In addition, encourages training of these personnel and confirmation that they have reached the required level of competence.
 

"Product quality" replaced by "conformity to product requirements."


  - 6.2.1 General
  - Personnel performing work affecting **conformity to product requirements (is amended from "product quality")** shall be competent on the basis of appropriate .....
  - NOTE** Conformity to product requirements may be affected **directly or indirectly by personnel performing any task within the quality management system. (Added)**
  - 6.2.2 Competence, **training and awareness (new sequence, alignment with ISO 14001:2004)**
    - a) determine the necessary competence for personnel performing work affecting **conformity to product requirements (is amended from "product quality")**,
    - b) **where applicable (Added)**, provide training or take other actions to **achieve the necessary competence (is amended from "satisfy these needs")**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 20

**SGS ISO 9001 : 2008 Amendment Highlights**


- 6.3 Infrastructure
- Highlighted changes:** Broadens the definition of support services and infrastructure to include information systems.
  - c) supporting services (such as transport, communication or **information systems (Added)**)
- 6.4 Work Environment
- Highlighted changes:** Clarifies that proper work environments for achieving conformity to product requirements, includes physical, environmental and other factors such as noise, temperature, humidity, lighting or weather.
  - A new note added for clarification
  - NOTE** The term "work environment" relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather). **(Added)**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 21

**SGS ISO 9001 : 2008 Amendment Highlights**


- 7.1 Planning of product realization
- Highlighted Changes:** Addition of "measurement" as one of the required activities to be determined during the planning of product realization
  - In planning product realization, the organization shall determine ...
  - c) required verification, validation, monitoring, **measurement (Added)**, inspection and test activities specific to the product and the criteria for product acceptance



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 22

**SGS ISO 9001 : 2008 Amendment Highlights**


- 7.2 Customer-related processes
- Highlighted Changes:** Minor vocabulary change slightly broadening the requirements for the product and the organization. Explanation given in relation to post delivery activities.
  - 7.2.1 Determination of requirements related to the product
    - c) statutory and regulatory requirements **applicable (is amended from "related")** to the product, and
    - d) any additional requirements **considered (is amended from "determined")** necessary by the organization.
    - NOTE** Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. **(Added)**



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 23

**SGS ISO 9001 : 2008 Amendment Highlights**

- 7.3 Design and development
- Highlighted changes:** Minor changes to the notes in this section for clarification. Includes the fact that review, verification and validation can be conducted separately or in any combination.
  - Information for production and service provision can include details for the preservation of product.
- 7.3.1 Design and development planning
  - NOTE** Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.
- 7.3.3 Design and development planning
  - The outputs of design and development shall be **in a form suitable for (formerly, provided in a form that enables) verification** against...
  - NOTE** Information for production and service provision can include details for the preservation of product.



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 24

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 7.5 Production and service provision

■ **Highlighted Changes:** Changes allow for the verification of a service after delivery. Ensuring that organizations monitor product status throughout the product realization process. Additional changes also broaden the definition of customer property to include personal data.

■ 7.5.1 Control of production and service provision

- d) the availability and use of monitoring and measuring **equipment, [is amended from "devices"]**
- e) the implementation of **product release [formerly, devices],** delivery and post-delivery activities

■ 7.5.2 Validation of processes for production and service provision

- The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement **and as a consequence [amended from "this includes any process where"],** deficiencies become apparent only after the product is in use or the service has been delivered.

SGS is the world's leading verification, testing and certification company 25

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 7.5.3 Identification and traceability

- The organization shall identify the product status with respect to monitoring and measurement requirements **throughout product realization, [Added]**
- Where traceability is a requirement, the organization shall control the unique identification of the product **and maintain records [see 4.2.4], [Re-phrasing only]**

■ 7.5.4 Customer property

- The organization shall exercise care with customer property ..... If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization **shall report this to the customer and maintain records [from: shall be reported to the customer and records maintained,]**
- **NOTE** Customer property can include intellectual property **and personal data [Added]**

SGS is the world's leading verification, testing and certification company 26

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 7.6 Control of monitoring and measuring **equipment [amended from "device"]**

■ **Highlighted Changes:** Broadens definition of monitoring and measuring equipment to include any equipment used to monitor conformance to product requirements. Now requires that records of calibration and/or verification are maintained. Note further clarifies the use of computer software.

■ a) be calibrated or verified, **or both [Added]**

■ c) have identification in order to determine its calibration status; **[Re-phrasing]**

■ **NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.**

SGS is the world's leading verification, testing and certification company 27

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 8.2 Monitoring and measurement

■ **Highlighted changes:** Minor changes include requirements to keep records of internal audits and their results.

In addition to determining the nature of the monitoring or measuring required to ensure product conformity, records of conformity shall be kept.

Note added providing examples as to how customer satisfaction can be determined.

Records indicating the person authorizing release of product for delivery to the customer have to be kept.

SGS is the world's leading verification, testing and certification company 28

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 8.2.1 Customer satisfaction

- **NOTE Monitoring customer perception may 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, [Added]**

■ 8.2.2 Internal audit

- A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results. **[Re-phrasing]**
- The management responsible for the area being audited shall ensure that **any necessary corrections and corrective [Added]** actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
- **Records of the audits and their results shall be maintained [See 4.2.4] [Added]**
- **NOTE See ISO19011 for guidance [Added]**

SGS is the world's leading verification, testing and certification company 29

**SGS ISO 9001 : 2008 Amendment Highlights**

■ 8.2.3 Monitoring and measurement of processes


- ... When planned results are not achieved, correction and corrective action shall be taken, as appropriate.
- **NOTE When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system [Added]**

SGS is the world's leading verification, testing and certification company 30

**SGS ISO 9001 : 2008 Amendment Highlights**

- 8.3 Control of Non-conforming product
- Highlighted changes:** Clarification that non-conforming products that have already been delivered or used shall be addressed.

- **Where applicable**, the organization shall deal with NC product by one or more of the following ways:
- ...
- **d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.** [Moved from end of paragraph, becoming an option for dealing with NC products]




SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 31

**SGS ISO 9001 : 2008 Amendment Highlights**

- 8.5 Corrective action and Preventive action
- Highlighted changes:** For both corrective and preventive action there is an updated clarification showing the need for reviewing the effectiveness of the corrective/preventive action taken.

- 8.5.2 / 3 Control of Non-conforming product
  - The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence.
  - f) reviewing **the effectiveness of the [added]** corrective action taken



SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 32

**SGS Overall Remarks of ISO9001:2008 Revisions**

- There are **no significant changes** to the requirements
- Most changes are in **terminologies** and **additional 'notes'** either seeking to clarify the intent, or aligning with other parts of the standard
- Certified organisations will need to review the detail of their system but should have to make no significant changes
- Transition** should be managed through the normal surveillance cycle with no additional time in most cases
- Auditor training should be **minimal** – requiring only familiarisation with the detail changes.

SGS is THE WORLD'S LEADING VERIFICATION, TESTING AND CERTIFICATION COMPANY 33

End of presentation

Thank You !

WHEN YOU NEED TO BE SURE 