WHAT IS ISO

ISO 9000 is a global standard related to Quality Management Objectives designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or service. The standards are published by ISO, the International Organization for Standardization, and available through National standards bodies. ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which the family of standards is based.

ISO 9001 deals with the requirements that organizations wishing to meet the standard have to fulfill.

Third party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over a million organizations worldwide are independently certified, making ISO 9001 one of the most widely used management tools in the world today.

Reasons for use

The global adoption of ISO 9001 may be attributable to a number of factors. A number of major purchasers require their suppliers to hold ISO 9001 certification. In addition to several stakeholders' benefits, a number of studies have identified significant financial benefits for organizations certified to ISO 9001, with a 2011 survey from the British Assessment Bureau showing 44% of their certified clients had won new business.

Advantages

It is widely acknowledged that proper quality management improves business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation. The quality principles in ISO 9000:2000 provide a comprehensive model for quality management systems that can make any company competitive. Implementing ISO often gives the following advantages:

1. creates a more efficient, effective operation
2. increases customer satisfaction and retention
3. reduces audits
4. enhances marketing
5. improves employee motivation, awareness, and morale
6. promotes international trade
7. increases profit
8. reduces waste and increases productivity
9. common tool for standardization.

Background

ISO 9000 was first published in 1987. It was based on the BS (British Standard) 5750 series of standards from that were proposed to ISO in 1979.

Worldwide total of ISO 9001 - Quality Management Systems - Requirements certificates											
Dec 2000	Dec 2001	Dec 2002	Dec 2003	Dec 2004	Dec 2005	Dec 2006	Dec 2007	Dec 2008	Dec 2009	Dec 2010	Dec 2011
457,834	510,349	561,767	497,919	660,132	773,867	896,929	951,486	982,832	1,064,785	1,118,510	1,111,698

In recent years there has been a rapid growth in China, which now accounts for approximately a quarter of the global certifications.

Top 10 countries for ISO 9001 certificates - 2011		
Rank	**Country**	**No. of certificates**
1	China	297,037
2	Italy	138,892
3	Russian Federation	62,265
4	Spain	59,854
5	Japan	59,287
6	Germany	50,583
7	United Kingdom	44,849
8	India	33,250
9	USA	25,101
10	Korea, Republic of	24,778

ISO 9001:2008 Quality management systems — Requirements is a document of approximately 30 pages which is available from the national standards organization in each country. It is supplemented by two other standards: ISO 9000:2005 *Quality management systems — Fundamentals and vocabulary* and ISO 9004:2009 *Managing for the sustained success of an organization — A quality management approach*. Only ISO 9001 is directly audited against for third party assessment purposes. The other two standards are supplementary and contain deeper information on how to sustain and improve quality management systems; they are therefore not used directly during third party assessment. Outline contents for ISO 9001 are as follows:

- Page iv: *Foreword*
- Pages v to vii: Section 0 *Intro*
- Pages 1 to 14: *Requirements*
  - Section 1: *Scope*
  - Section 2: *Normative Reference*

- o Section 3: *Terms and definitions* (specific to ISO 9001, not specified in ISO 9000)
  - o Section 4: *Quality Management System*
  - o Section 5: *Management Responsibility*
  - o Section 6: *Resource Management*
  - o Section 7: *Product Realization*
  - o Section 8: *Measurement, analysis and improvement*
- Pages 15 to 22: Tables of Correspondence between ISO 9001 and other standards
- Page 23: *Bibliography*

Before the certification body can issue or renew a certificate, the auditor must be satisfied that the company being assessed has implemented the requirements of sections 4 to 8. Sections 1 to 3 are not directly audited against, but because they provide context and definitions for the rest of the standard, their contents must be taken into account.

The standard specifies that the organisation shall issue and maintain the following six documented procedures:

- Control of Documents (4.2.3)
- Control of Records (4.2.4)
- Internal Audits (8.2.2)
- Control of Nonconforming Product / Service (8.3)
- Corrective Action (8.5.2)
- Preventive Action (8.5.3)

In addition to these procedures, ISO 9001:2008 requires the organization to document any other procedures required for its effective operation. The standard also requires the organisation to issue and communicate a documented quality policy, a Quality Manual (which may or may not include the documented procedures) and numerous records, as specified throughout the standard.

Numbering

- 4.2 Documentation requirements
- **5 Management responsibility**
- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
- 5.5 Responsibility, authority and communication
- 5.6 Management review
- **6 Resource management**
- 6.1 Provision of resources
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work environment
- **7 Product realization**
- 7.1 Planning of product realization
- 7.2 Customer-related processes

- 7.3 Design and development
- 7.4 Purchasing
- 7.5 Production and service provision
- 7.6 Control of monitoring and measuring equipment
- **8 Measurement, analysis and improvement**
- 8.1 General
- 8.2 Monitoring and measurement
- 8.3 Control of nonconforming product
- 8.4 Analysis of data
- 8.5 Improvement

- The quality policy is a formal statement from management, closely linked to the business and marketing plan and to customer needs.
- The quality policy is understood and followed at all levels and by all employees. Each employee works towards measurable objectives.
- The business makes decisions about the quality system based on recorded data.
- The quality system is regularly audited and evaluated for conformance and effectiveness.
- Records show how and where raw materials and products were processed to allow products and problems to be traced to the source.

- The business determines customer requirements.
- The business has created systems for communicating with customers about product information, inquiries, contracts, orders, feedback, and complaints.
- When developing new products, the business plans the stages of development, with appropriate testing at each stage. It tests and documents whether the product meets design requirements, regulatory requirements, and user needs.
- The business regularly reviews performance through internal audits and meetings. The business determines whether the quality system is working and what improvements can be made. It has a documented procedure for internal audits.
- The business deals with past problems and potential problems. It keeps records of these activities and the resulting decisions, and monitors their effectiveness.
- The business has documented procedures for dealing with actual and potential non-conformances (problems involving suppliers, customers, or internal problems).
- The business:
  1. makes sure no one uses a bad product,
  2. determines what to do with a bad product,
  3. deals with the root cause of problems, and
  4. keeps records to use as a tool to improve the system.

ISO does not certify organizations itself. Numerous certification bodies exist, which audit organizations and, upon success, issue ISO 9001 compliance certificates. Although commonly referred to as 'ISO 9000' certification, the actual standard to which an organization's quality management system can be certified is ISO 9001:2008. Many countries have formed accreditation bodies to authorize ("accredit") the certification bodies. Both the accreditation bodies and the certification bodies charge fees for their services. The various accreditation

bodies have mutual agreements with each other to ensure that certificates issued by one of the Accredited Certification Bodies (CB) are accepted worldwide. Certification bodies themselves operate under another quality standard, ISO/IEC 17021, while accreditation bodies operate under ISO/IEC 17011.

An organization applying for ISO 9001 certification is audited based on an extensive sample of its sites, functions, products, services and processes. The auditor presents a list of problems (defined as "nonconformities", "observations" or "opportunities for improvement") to management. If there are no major nonconformities, the certification body will issue a certificate. Where major nonconformities are identified, the organization will present an improvement plan to the certification body (e.g. corrective action reports showing how the problems will be resolved); once the certification body is satisfied that the organisation has carried out sufficient corrective action, it will issue a certificate. The certificate is limited by a certain scope (e.g. production of golf balls) and will display the addresses to which the certificate refers.

An ISO 9001 certificate is not a once-and-for-all award, but must be renewed at regular intervals recommended by the certification body, usually once every three years. There are no grades of competence within ISO 9001: either a company is certified (meaning that it is committed to the method and model of quality management described in the standard) or it is not. In this respect, ISO 9001 certification contrasts with measurement-based quality systems.

Auditing

Two types of auditing are required to become registered to the standard: auditing by an external certification body (external audit) and audits by internal staff trained for this process (internal audits). The aim is a continual process of review and assessment to verify that the system is working as it is supposed to; to find out where it can improve; and to correct or prevent problems identified. It is considered healthier for internal auditors to audit outside their usual management line, so as to bring a degree of independence to their judgments.

Under the 1994 standard, the auditing process could be adequately addressed by performing "compliance auditing":

- Tell me what you do *(describe the business process)*
- Show me where it says that *(reference the procedure manuals)*
- Prove that this is what happened *(exhibit evidence in documented records)*

The 2000 standard uses a different approach. Auditors are expected to go beyond mere auditing for rote compliance by focusing on risk, status, and importance. This means they are expected to make more judgments on what is effective, rather than merely adhering to what is formally prescribed. The difference from the previous standard can be explained thus:

Under the 1994 version, the question was broad: "Are you doing what the manual says you should be doing?", whereas under the 2000 version, the questions are more specific: "Will this process help you achieve your stated objectives? Is it a good process or is there a way to do it better?