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# Orientation Training Program

## What is ISO 9000 ?

**ISO 9000** is a family of standards for quality management systems. ISO 9000 is maintained by ISO, the International Organization for Standardization and is administered by accreditation and certification bodies. Some of the requirements in ISO 9001 (which is one of the standards in the ISO 9000 family) include:

- a set of procedures that cover all key processes in the business;
- monitoring processes to ensure they are effective;
- keeping adequate records;
- checking output for defects, with appropriate and corrective action where necessary;
- regularly reviewing individual processes and the quality system itself for effectiveness; and
- facilitating continual improvement

A company or organization that has been independently audited and certified to be in conformance with ISO 9001 may publicly state that it is "ISO 9001 certified" or "ISO 9001 registered". Certification to an ISO 9000 standard does not guarantee any quality of end products and services; rather, it certifies that formalized business processes are being applied. Indeed, some companies enter the ISO 9001 certification as a marketing tool.

Although the standards originated in manufacturing, they are now employed across several types of organization. A "product", in ISO vocabulary, can mean a physical object, services, or software. In fact, according to ISO in 2004, *"service sectors now account by far for the highest number of ISO 9001:2000 certificates - about 31% of the total."*

### ISO 9000 family & standards:

**ISO 9000:2000, Quality management systems – Fundamentals and vocabulary.** Covers the basics of what quality management systems are and also contains the core language of the ISO 9000 series of standards. A guidance document, not used for certification purposes, but important reference document to understand terms and vocabulary related to quality management systems. In the year 2005, revised ISO 9000:2005 standards has been published, so it is now advised to refer to ISO 9000:2005.

**ISO 9001:2000 Quality management systems – Requirements** is intended for use in any organization which designs, develops, manufactures, installs and/or services any product or provides any form of service. It provides a number of requirements which an organization needs to fulfill if it is to achieve customer satisfaction through consistent products and services which meet customer expectations. It includes a requirement for the continual (i.e. planned) improvement of the Quality Management System, for which ISO 9004:2000 provides many hints.

This is the only implementation for which third-party auditors may grant certification. It should be noted that certification is not described as any of the 'needs' of an organization as a driver for using ISO 9001 but does recognize that it may be used for such a purpose.

**ISO 9004:2000 Quality management systems - Guidelines for performance improvements.** covers continual improvement. This gives you advice on what you could do to enhance a mature system. This standard very specifically states that it is not intended as a guide to implementation.

There are many more standards in the **ISO 9001 family**, many of them not even carrying "ISO 900x" numbers. For example, some standards in the 10,000 range are considered part of the 9000 family: ISO 0007:1995 discusses Configuration management, which for most organizations is just one element of a complete management system. ISO notes: "The emphasis on certification tends to overshadow the fact that there is an entire family of ISO 9000 standards ... Organizations stand to obtain the greatest value when the standards in the new core series are used in an integrated manner, both with each other and with the other standards making up the ISO 9000 family as a whole".

Note that the previous members of the ISO 9000 family, 9001, 9002 and 9003, have all been integrated into 9001. In most cases, an organization claiming to be "ISO 9000 registered" is referring to ISO 9001.

## **Contents of ISO 9001**

*ISO 9001:2000 Quality management systems — Requirements* is a document of approximately 30 pages which is available from the national standards organization in each country.

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 needs measurable objectives to work towards.

-Decisions about the quality system are made based on recorded data and the system is regularly audited and evaluated for conformance and effectiveness.

-Records should show how and where raw materials and products were processed, to allow products and problems to be traced to the source.

-You need a documented procedure to control quality documents in your company. Everyone must have access to up-to-date documents and be aware of how to use them.

-To maintain the quality system and produce conforming product, you need to provide suitable infrastructure, resources, information, equipment, measuring and monitoring devices, and environmental conditions.

-You need to map out all key processes in your company; control them by monitoring, measurement and analysis; and ensure that product quality objectives are met. If you can't monitor a process by measurement, then make sure the process is well enough defined that you can make adjustments if the product does not meet user needs.

-For each product your company makes, you need to establish quality objectives; plan processes; and document and measure results to use as a tool for improvement. For each process, determine what kind of procedural documentation is required (note: a "product" is hardware, software, services, processed materials, or a combination of these).

- You need to determine key points where each process requires monitoring and measurement, and ensure that all monitoring and measuring devices are properly maintained and calibrated.
- You need to have clear requirements for purchased product.
- You need to determine customer requirements and create systems for communicating with customers about product information, inquiries, contracts, orders, feedback and complaints.
- When developing new products, you need to plan the stages of development, with appropriate testing at each stage. You need to test and document whether the product meets design requirements, regulatory requirements and user needs.
- You need to regularly review performance through internal audits and meetings. Determine whether the quality system is working and what improvements can be made. Deal with past problems and potential problems. Keep records of these activities and the resulting decisions, and monitor their effectiveness (note: you need a documented procedure for internal audits).
- You need documented procedures for dealing with actual and potential nonconformances (problems involving suppliers or customers, or internal problems). Make sure no one uses bad product, determine what to do with bad product, deal with the root cause of the problem and keep records to use as a tool to improve the system.

ISO 9000:1987 had the same structure as the UK Standard BS 5750, with three 'models' for quality management systems, the selection of which was based on the scope of activities of the organization:

ISO 9001:1987 Model for quality assurance in design, development, production, installation, and servicing was for companies and organizations whose activities included the creation of new products.

ISO 9002:1987 Model for quality assurance in production, installation, and servicing had basically the same material as ISO 9001 but without covering the creation of new products.

ISO 9003:1987 Model for quality assurance in final inspection and test covered only the final inspection of finished product, with no concern for how the product was produced.

ISO 9000:1987 was also influenced by existing U.S. and other Defense Standards ("MIL SPECS"), and so was well-suited to manufacturing. The emphasis tended to be placed on conformance with procedures rather than the overall process of management—which was likely the actual intent.  
1994 version

ISO 9000:1994 emphasized quality assurance via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures. As with the first edition, the down-side was that companies tended to implement its requirements by creating shelf-loads of procedure manuals, and becoming burdened with an ISO bureaucracy. In some companies, adapting and improving processes could actually be impeded by the quality system.

ISO 9001:2000 combines the three standards 9001, 9002, and 9003 into one, called 9001. Design and development procedures are required only if a company does in fact engage in the creation of new products. The 2000 version sought to make a radical change in thinking by actually placing the concept of process management front and center ("Process management" was the monitoring and optimizing of a company's tasks and activities, instead of just inspecting the final product). The 2000 version also demands involvement by upper executives, in order to integrate quality into the business system and avoid delegation of quality functions to junior administrators. Another goal is to improve effectiveness via process performance metrics — numerical measurement of the effectiveness of tasks and activities. Expectations of continual process improvement and tracking customer satisfaction were made explicit.

The ISO 9000 standard is continually being revised by standing technical committees and advisory groups, who receive feedback from those professionals who are implementing the standard.

ISO 9001:2008 only introduces clarifications to the existing requirements of ISO 9001:2000 and some changes intended to improve consistency with ISO 14001:2004. There are no new requirements. A quality management system being upgraded just needs to be checked to see if it is following the clarifications introduced in the amended version.

### **Certification**

ISO does not itself certify organizations. Many countries have formed accreditation bodies to authorize certification bodies, which audit organizations applying for ISO 9001 compliance certification. Although commonly referred to as ISO 9000:2000 certifications, the actual standard to which an organization's quality management can be certified is ISO 9001:2000. 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.

The applying organization is assessed based on an extensive sample of its sites, functions, products, services and processes; a list of problems ("action requests" or "non-compliances") is made known to the management. If there are no major problems on this list, the certification body will issue an ISO 9001 certificate for each geographical site it has visited, once it receives a satisfactory improvement plan from the management showing how any problems will be resolved.

An ISO certificate is not a once-and-for-all award, but must be renewed at regular intervals recommended by the certification body, usually around three years. In contrast to the Capability Maturity Model there are no grades of competence within ISO 9001.

### **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's supposed 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 that is what happened (*exhibit evidence in documented records*)

How this led to preventive actions was not clear. The 2000 standard uses the process approach. While auditors perform similar functions, they 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 broadly "Are you doing what the manual says you should be doing?" whereas under the 2000 version, the question is more "Will this process help you achieve your stated objectives? Is it a good process or is there a way to do it better?"

## **Industry-specific interpretations**

The ISO 9001 standard is generalized and abstract. Its parts must be carefully interpreted, to make sense within a particular organization. Developing software is not like making cheese or offering counseling services; yet the ISO 9001 guidelines, because they are business management guidelines, can be applied to each of these. Diverse organizations—police departments (US), professional soccer teams (Mexico) and city councils (UK)—have successfully implemented ISO 9001:2000 systems.

Over time, various industry sectors have wanted to standardize their interpretations of the guidelines within their own marketplace. This is partly to ensure that their versions of ISO 9000 have their specific requirements, but also to try and ensure that more appropriately trained and experienced auditors are sent to assess them.

- The TickIT guidelines are an interpretation of ISO 9000 produced by the UK Board of Trade to suit the processes of the information technology industry, especially software development.
- AS9000 is the Aerospace Basic Quality System Standard, an interpretation developed by major aerospace manufacturers. Those major manufacturers include AlliedSignal, Allison Engine, Boeing, General Electric Aircraft Engines, Lockheed-Martin, McDonnell Douglas, Northrop Grumman, Pratt & Whitney, Rockwell-Collins, Sikorsky Aircraft, and Sundstrand. The current version is AS9100.
- PS 9000 is an application of the standard for Pharmaceutical Packaging Materials. The Pharmaceutical Quality Group (PQG) of the Institute of Quality Assurance (IQA) has developed PS 9000:2001. It aims to provide a widely accepted baseline GMP framework of best practice within the pharmaceutical packaging supply industry. It applies ISO 9001: 2000 to pharmaceutical printed and contact packaging materials.
- QS 9000 is an interpretation agreed upon by major automotive manufacturers (GM, Ford, and Chrysler). It includes techniques such as FMEA and APQP. QS 9000 is now replaced by ISO/TS 16949.
- ISO/TS 16949:2002 is an interpretation agreed upon by major automotive manufacturers (American and European manufacturers); the latest version is based on ISO 9001:2000. The emphasis on a process approach is stronger than in ISO 9001:2000. ISO/TS 16949:2002 contains the full text of ISO 9001:2000 and automotive industry-specific requirements.
- TL 9000 is the Telecom Quality Management and Measurement System Standard, an interpretation developed by the telecom consortium, QuEST Forum. The current version is 4.0 and unlike ISO 9001 or the above sector standards, TL 9000 includes standardized product measurements that can be benchmarked. In 1998 QuEST Forum developed the TL 9000 Quality Management System to meet the supply chain quality requirements of the worldwide telecommunications industry.
- ISO 13485:2003 is the medical industry's equivalent of ISO 9001:2000. Whereas the standards it replaces were interpretations of how to apply ISO 9001 and ISO 9002 to medical devices, ISO 13485:2003 is a stand-alone standard. Compliance with ISO 13485 does not necessarily mean compliance with ISO 9001:2000.

## **Debate on the effectiveness of ISO 9000**

The debate on the effectiveness of ISO 9000 commonly centers on the following questions:

Are the quality principles in ISO 9001:2000 of value? (Note that the version date is important: in the 2000 version ISO attempted to address many concerns and criticisms of ISO 9000:1994).

- Does it help to implement an ISO 9001:2000 compliant quality management system?
- Does it help to obtain ISO 9001:2000 certification?

## **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 are also sound and ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive. According to *the Providence Business News*<sup>[6]</sup>, implementing ISO often gives the following advantages:

- Create a more efficient, effective operation
- Increase customer satisfaction and retention
- Reduce audits
- Enhance marketing
- Improve employee motivation, awareness, and morale

- Promote international trade
- Increases profit
- Reduce waste and increases productivity

However, a broad statistical study of 800 Spanish companies found that ISO 9000 registration in itself creates little improvement because companies interested in it have usually already made some type of commitment to quality management and were performing just as well before registration.<sup>[3]</sup>

In today's service-sector driven economy, more and more companies are using ISO 9000 as a business tool. Through the use of properly stated quality objectives, customer satisfaction surveys and a well-defined continual improvement program companies are using ISO 9000 processes to increase their efficiency and profitability.

### **Problems**

A common criticism of ISO 9001 is the amount of money, time and paperwork required for registration. Opponents claim that it is only for documentation. Proponents believe that if a company has documented its quality systems, then most of the paperwork has already been completed.

Others believe that ISO 9001 promotes specification, control, and procedures rather than understanding and improvement and that ISO 9000 is effective as a guideline, and that promoting it as a standard "helps to mislead companies into thinking that certification means better quality... [Undermining] the need for an organization to set its own quality standards." Paraphrased, others argue that conforming to specifications of ISO 9001 does not guarantee a successful quality system.

The standard is seen as especially prone to failure when a company is interested in certification before quality. Certifications are in fact often based on customer contractual requirements rather than a desire to actually improve quality. For example, "If you just want the certificate on the wall, chances are, you will create a paper system that doesn't have much to do with the way you actually run your business," said ISO's Roger Frost. Certification by an independent auditor is often seen as the problem area and can become a self full filling vehicle to increase consulting services. In fact, ISO itself advises that ISO 9001 can be implemented without certification, simply for the quality benefits that can be achieved, unless one's customer requires a certificate from a third part auditor.