

# ISO 9000

The **ISO 9000** family of **quality management systems** standards is 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.<sup>[1]</sup> ISO 9000 deals with the fundamentals of quality management systems,<sup>[2]</sup> including the eight management principles upon which the family of standards is based.<sup>[2]</sup> <sup>[3][4]</sup> ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill.<sup>[5]</sup>

Third-party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over one million organizations worldwide<sup>[6]</sup> are independently certified, making ISO 9001 one of the most widely used management tools in the world today. However, the ISO certification process has been criticized<sup>[7][8]</sup> as being wasteful and not being useful for all organizations.<sup>[9][10]</sup>

## 1 Background

ISO 9000 was first published in 1987.<sup>[11]</sup> It was based on the BS 5750 series of standards from BSI that were proposed to ISO in 1979.<sup>[12]</sup> However, its history can be traced back some twenty years before that, to the publication of the United States Department of Defense MIL-Q-9858 standard in 1959. MIL-Q-9858 was revised into the NATO AQAP series of standards in 1969, which in turn were revised into the BS 5179 series of guidance standards published in 1974, and finally revised into the BS 5750 series of requirements standards in 1979 before being submitted to ISO.

## 2 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.<sup>[13]</sup> Corbett *et al.* showed that certified organizations achieved superior **return on assets**<sup>[14]</sup> compared to otherwise similar organizations without certification.<sup>[15]</sup> Heras *et al.* found similarly superior performance<sup>[16]</sup> and demonstrated that

this was statistically significant and not a function of organization size.<sup>[17]</sup> Naveha and Marcus claimed that implementing ISO 9001 led to superior operational performance in the **U.S. automotive industry**.<sup>[18]</sup> Sharma identified similar improvements in operating performance and linked this to superior financial performance.<sup>[19]</sup> Chow-Chua *et al.* showed better overall financial performance was achieved for companies in **Denmark**.<sup>[20]</sup> Rajan and Tamimi (2003) showed that ISO 9001 certification resulted in superior stock market performance and suggested that shareholders were richly rewarded for the investment in an ISO 9001 system.<sup>[21]</sup>

While the connection between superior financial performance and ISO 9001 may be seen from the examples cited, there remains no proof of direct causation, though **longitudinal studies**, such as those of Corbett *et al.* (2005)<sup>[15]</sup> may suggest it. Other writers, such as Heras *et al.* (2002),<sup>[17]</sup> have suggested that while there is some evidence of this, the improvement is partly driven by the fact that there is a tendency for better performing companies to seek ISO 9001 certification.

The mechanism for improving results has also been the subject of much research. Lo *et al.* (2007) identified operational improvements (e.g., cycle time reduction, inventory reductions) as following from certification. Internal process improvements in organizations lead to externally observable improvements.<sup>[22][23]</sup> The benefit of increased international trade and domestic market share, in addition to the internal benefits such as customer satisfaction, interdepartmental communications, work processes, and customer/supplier partnerships derived, far exceeds any and all initial investment.<sup>[24]</sup>

## 3 Global adoption

The increase in ISO 9001 certification is shown in the tables below.

## 4 ISO 9000 series Quality management principles

The ISO 9000 series are based on eight quality management principles.

The eight quality management principles are defined in ISO 9000:2005, Quality management systems – Funda-

mentals and vocabulary, and in ISO 9004:2009, Managing for the sustained success of an organization – A quality management approach.<sup>[3]</sup>

#### Principle 1 – Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

#### Principle 2 – Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

#### Principle 3 – Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

#### Principle 4 – Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

#### Principle 5 – System approach to management

Identifying, understanding and managing inter-related processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

#### Principle 6 – Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

#### Principle 7 – Factual approach to decision making

Effective decisions are based on the analysis of data and information.

#### Principle 8 – Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.



A fish wholesaler in Tsukiji, Japan advertising its ISO 9001 certification.

## 5 Contents of ISO 9001:2015

*ISO 9001:2015 Quality management systems — Requirements* is a document of approximately 30 pages which is available from the national standards organization in each country. Only ISO 9001 is directly audited against for third party assessment purposes. Outline requirements for ISO 9001:2015 are as follows:

- *Requirements*
  - Section 4: Context of the Organization
  - Section 5: Leadership
  - Section 6: Planning
  - Section 7: Support
  - Section 8: Operation
  - Section 9: Performance evaluation
  - Section 10: Improvement

Essentially the layout of the standard is similar to the previous ISO 9001:2008 standard in that it follows the **Plan, Do, Check, Act** cycle in a process based approach, but is now further encouraging this to have risk based thinking. (section 0.3.3 of the introduction)

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 10. Sections 1 to 3 are not directly audited against, but because they provide context and definitions for the rest of the standard, not that of the organization, their contents must be taken into account.

The standard no longer specifies that the organization shall issue and maintain documented procedures, however ISO 9001:2015 requires the organization to docu-

ment any other procedures required for its effective operation. The standard also requires the organization to issue and communicate a documented **quality policy**, a Quality Manual (which may or may not include documented procedures) and numerous records, as specified throughout the standard. New for the 2015 release is a requirement for an organization to assess risks and opportunities (section 6.1) and to determine internal and external issues relevant to its purpose and strategic direction (section 4.1) Interpretations of how the standards requirements are a matter for the organization to demonstrate, and an external auditor to determine, the effectiveness of a quality management system. Further detail, interpretation and examples of implementation are often sought by organizations seeking more information in what can be seen as a very technical area.

## 6 Certification

International Organization for Standardization (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 9001:2015 (ISO 9001:2008 will expire by around September 2018). 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,<sup>[32]</sup> while accreditation bodies operate under ISO/IEC 17011.<sup>[33]</sup>

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 organization 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.

## 7 Evolution of ISO 9000 standards

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.

### 7.1 1987 version

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.

### 7.2 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 downside 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.

### 7.3 2000 version

ISO 9001:2000 replaced all three former standards of 1994 issue, *ISO 9001*, *ISO 9002* and *ISO 9003*. Design and development procedures were 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 front and centre the concept of **process management** (the monitoring and optimisation of a company's tasks and activities, instead of just inspection of the final product). The 2000 version also demanded involvement by upper executives in order to integrate quality into the business system and avoid delegation of quality functions to junior administrators. Another goal was 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.

ISO 9000 Requirements include:

- Approve documents before distribution;
- Provide correct version of documents at points of use;
- Use your records to prove that requirements have been met; and
- Develop a procedure to control your records.

### 7.4 2008 version

ISO 9001:2008 in essence re-narrates ISO 9001:2000. The 2008 version only introduced clarifications to the existing requirements of ISO 9001:2000 and some changes intended to improve consistency with ISO 14001:2004. There were no new requirements. For example, in ISO 9001:2008, a quality management system being upgraded just needs to be checked to see if it is following the clarifications introduced in the amended version.

ISO 9001 is supplemented directly by two other standards of the family:

- ISO 9000:2005 “Quality management systems. Fundamentals and vocabulary”
- ISO 9004:2009 “Managing for the sustained success of an organization. A quality management approach”

Other standards, like ISO 19011 and the ISO 10000 series, may also be used for specific parts of the quality system.

### 7.5 2015 version

In 2012, ISO TC 176 - responsible for ISO 9001 development - celebrated 25 years of implementing ISO 9001,<sup>[34]</sup> and concluded that it is necessary to create a new QMS model for the next 25 years. This is why they commenced the official work on creating a revision of ISO 9001, starting with the new QM principles. This moment was considered by important specialists in the field as “beginning of a new era in the development of quality management systems.”<sup>[35]</sup> As a result of the intensive work from this technical committee, the revised standard ISO 9001:2015 was published by ISO on 23 September 2015. The scope of the standard has not changed, however, the structure and core terms were modified to allow the standard to integrate more easily with other international management systems standards.

The 2015 version is also less prescriptive than its predecessors and focuses on performance. This was achieved by combining the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization.<sup>[36]</sup>

Some of the key changes include:

- Greater emphasis on building a management system suited to each organization's particular needs
- A requirement that those at the top of an organization be involved and accountable, aligning quality with wider business strategy
- Risk-based thinking throughout the standard makes the whole management system a preventive tool and encourages continuous improvement
- Less prescriptive requirements for documentation: the organization can now decide what documented information it needs and what format it should be in
- Alignment with other key management system standards through the use of a common structure and core text<sup>[37]</sup>

## 8 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 “conformance 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 conformance 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?”

## 9 Industry-specific interpretations

The ISO 9001 standard is generic; 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 (United States), 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 **AS9100C**.

- **PS 9000 \* QS 9000** is an interpretation agreed upon by major automotive manufacturers (GM, Ford, Chrysler). It includes techniques such as **FMEA** and **APQP**. QS 9000 is now replaced by ISO/TS 16949.
- **ISO/TS 16949:2009** is an interpretation agreed upon by major automotive manufacturers (American and European manufacturers); the latest version is based on ISO 9001:2008. The emphasis on a process approach is stronger than in ISO 9001:2008. ISO/TS 16949:2009 contains the full text of ISO 9001:2008 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**. In 1998 QuEST Forum developed the TL 9000 Quality Management System to meet the supply chain quality requirements of the worldwide telecommunications industry. The TL 9000 standard is made up of two handbooks: the QMS Requirements Handbook, and the QMS Measurement Handbook. The current versions of the Requirements and Measurements Handbooks are 5.0. Unlike ISO 9001 or other sector-specific standards, TL 9000 includes standardized product and process measurements that must be reported into a central repository, which allow organizations to benchmark their performance in key process areas against peer organizations. It is important to note that TL 9000 R5.0 contains the full text of ISO 9001:2008.
- **ISO 13485:2012** is the medical industry’s equivalent of ISO 9001:2008. 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. Because ISO 13485 is relevant to medical devices manufacturers (unlike ISO 9001, which is applicable to any industry), and because of the differences between the two standards relating to continual improvement, compliance with ISO 13485 does not necessarily mean compliance with ISO 9001:2008 (and vice versa).
- **ISO/IEC 90003:2014** provides guidelines for the application of ISO 9001:2008 to computer software.
- **ISO/TS 29001** is quality management system requirements for the design, development, production, installation, and service of products for the petroleum, petrochemical, and natural gas industries. It is equivalent to API Spec Q1 without the Monogram annex.

## 10 Effectiveness

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

1. Are the quality principles in ISO 9001 of value?
2. Does it help to implement an ISO 9001-compliant quality management system?
3. Does it help to obtain ISO 9001 certification?

Effectiveness of the ISO system being implemented depends on a number of factors, the most significant of which are:

1. Commitment of senior management to monitor, control, and improve quality. Organizations that implement an ISO system without this desire and commitment often take the cheapest road to get a certificate on the wall and ignore problem areas uncovered in the audits.
2. How well the ISO system integrates into current business practices. Many organizations that implement ISO try to make their system fit into a cookie-cutter quality manual instead of creating a manual that documents existing practices and only adds new processes to meet the ISO standard when necessary.
3. How well the ISO system focuses on improving the customer experience. The broadest definition of quality is “Whatever the customer perceives good quality to be.” This means that a company doesn't necessarily have to make a product that never fails; some customers will have a higher tolerance for product failures if they always receive shipments on-time or have a positive experience in some other dimension of customer service. An ISO system should take into account all areas of the customer experience and the industry expectations, and seek to improve them on a continual basis. This means taking into account all processes that deal with the three stakeholders (customers, suppliers, and organization); only then will a company be able to sustain improvements in the customer's experience.
4. How well the auditor finds and communicates areas of improvement. While ISO auditors may not provide consulting to the clients they audit, there is the potential for auditors to point out areas of improvement. Many auditors simply rely on submitting reports that indicate compliance or non-compliance with the appropriate section of the standard; however, to most executives, this is like speaking a foreign language. Auditors that can clearly identify and communicate areas of improvement in language and terms executive management understands facilitate action on improvement initiatives by the companies they audit. When management doesn't understand why they were non-compliant and the business implications associated with non-compliance, they simply ignore the reports and focus on what they do understand.

## 10.1 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.<sup>[38]</sup> The quality principles in ISO 9000:2000 are also sound, according to Wade<sup>[39]</sup> and Barnes, who says that “ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive”.<sup>[40]</sup> Sroufe and Curkovic, (2008) found benefits ranging from registration required to remain part of a supply base, better documentation, to cost benefits, and improved involvement and communication with management.<sup>[38]</sup> 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
10. Enables to meet the requirements of an internationally uniform quality system.
11. Motivates the employees and develops pride in them for achieving excellence.

## 10.2 Criticisms of ISO 9000

A common criticism of ISO 9000 and 9001 is the amount of money, time, and paperwork required for registration.<sup>[7]</sup> Dagleish cites the “inordinate and often unnecessary paperwork burden” of ISO, and says that “quality managers feel that ISO's overhead and paperwork are excessive and extremely inefficient”.<sup>[41]</sup>

According to Barnes, “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”.<sup>[40]</sup> Wilson suggests that ISO standards “elevate inspection of the correct procedures over broader aspects of quality”, and therefore, “the workplace becomes oppressive and quality is not improved”.<sup>[8]</sup>

One study showing reasons for not adopting this standard include the risks and uncertainty of not knowing if there

are direct relationships to improved quality, and what kind and how many resources will be needed. Additional risks include how much certification will cost, increased bureaucratic processes and risk of poor company image if the certification process fails.<sup>[38]</sup> According to John Seddon, ISO 9001 promotes specification, control, and procedures rather than understanding and improvement.<sup>[9]</sup> Wade argues that ISO 9000 is effective as a guideline, but 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”.<sup>[39]</sup> In short, Wade argues that reliance on the 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.<sup>[9]</sup> Certifications are in fact often based on customer contractual requirements rather than a desire to actually improve quality.<sup>[40][42]</sup> “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.<sup>[42]</sup> Certification by an independent auditor is often seen as the problem area, and according to Barnes, “has become a vehicle to increase consulting services”.<sup>[40]</sup>

Dalgleish argues that while “quality has a positive effect on return on investment, market share, sales growth, better sales margins and competitive advantage”, that “taking a quality approach is unrelated to ISO 9000 registration”.<sup>[43]</sup> In fact, ISO itself advises that ISO 9001 can be implemented without certification, simply for the quality benefits that can be achieved.<sup>[44]</sup>

Abrahamson argues that fashionable management discourse such as Quality Circles tends to follow a lifecycle in the form of a bell curve, possibly indicating a management fad.<sup>[45]</sup>

Pickrell argues that ISO systems merely gauge whether the processes are being followed. It does not gauge how good the processes are or whether the correct parameters are being measured and controlled to ensure quality. Furthermore, when unique technical solutions are involved in the creation of a new part, ISO does not validate the robustness of the technical solution which is a key part of advanced quality planning. It is not unheard of for an ISO-certified plant to display poor quality performance due to poor process selection and/or poor technical solutions.

## 11 See also

- Conformity assessment—Containing ISO published standards
- ISO 10006—Quality management—Guidelines to quality management in projects

- ISO 14001—Environmental management standards
- ISO 19011—Guidelines for quality management systems auditing and environmental management systems auditing
- ISO/TS 16949—Quality management system requirements for automotive-related products suppliers
- ISO/IEC 27001—Information security management
- ISO 39001—Road traffic safety management
- ISO 50001—Energy Audit
- AS 9100 - aerospace industry implementation of ISO 9000/1
- List of ISO standards
- ISO/TC 176
- Quality management system
- Test management
- Verification and Validation
- International Organization for Standardization

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## 13 Further reading

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## 14 External links

- Official website
- ISO/TC 176, SC 2 - ISO committee responsible for developing ISO 9000 standards

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