6. Iso 9000

The **ISO 9000** family of standards is related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to the product. 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.[4]

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. Despite widespread use, however, the ISO certification process has been criticized as being wasteful and not being useful for all organizations.

6.1 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. Corbett et al. showed that certified organizations achieved superior return on assetscompared to otherwise similar organizations without certification. Heras et al. found similarly superior performanceand demonstrated that this was statistically significant and not a function of organization size. Naveha and Marcus claimed that implementing ISO 9001 led to superior operational performance in the US motor carrier industry. Sharma identified similar improvements in operating performance and linked this to superior financial performance. Chow-Chua et al. showed better overall financial performance was achieved for companies in Denmark. 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.

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) may suggest it. Other writers, such as Heras et al. (2002), 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 (cycle time reduction, inventory reductions, etc.) as following from certification. Internal process improvements in organizations lead to externally observable improvements. 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.

6.2 Background

ISO 9000 was first published in 1987. It was based on the BS 5750 series of standards from BSIthat were proposed to ISO in 1979. 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.

BSI has been certifying organizations for their quality management systems since 1978. Its first certification (FM 00001) is still extant and held by Tarmac Limited, a successor to the original company which held this certificate. Today BSI claims to certify organizations at nearly 70,000 sites globally.

6.3 Contents of ISO 9001

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
    - Section 3: Terms and definitions (specific to ISO 9001, not specified in ISO 9000)
    - Section 4: Quality Management System
    - Section 5: Management Responsibility
    - Section 6: Resource Management
    - Section 7: Product Realization
    - 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.

6.4 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

6.5 Summary of ISO 9001:2008 in informal language

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 nonconformances (problems involving suppliers, customers, or internal problems).

The business:

makes sure no one uses a bad product,

determines what to do with a bad product,

deals with the root cause of problems, and

keeps records to use as a tool to improve the system.

6.6 Certification

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