

# ISO 9001, Quality Management System

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Every 5 years or so, the ISO series of documents is reviewed and revised. The previous version was from 2000. The latest revision is 2008. This standard is a model used by organizations around the world and applies to all types and sizes of businesses. It also enables customers to assess suppliers on an equal basis. Some customers require ISO 9001 certification in order to do business with them. A 3<sup>rd</sup> party registrar is required to conduct an independent audit for certification.

The standard has only 5 major sections. The clauses are: 1. Quality Management System, 2. Management Responsibility, 3. Resource Management, 4. Product Realization and 5. Measurement, analysis and improvement.

The model of the process based system is shown below. This illustration shows that the customers play a significant role in defining requirements as inputs. Monitoring customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements.

## Outline of the different Clauses:

**Quality Management System** outlines the general documentation requirements, control of documents and control of records.

**Management Responsibility** outlines management commitment, customer focus, quality policy and quality planning. It also discusses responsibility, authority and communication along with management review of the organization's quality management system.

**Resource management** outlines the resources required, training, infrastructure and work environment.

**Product Realization** outlines the quality planning requirements, determination of customer processes, product requirements, customer communication, design and development, purchasing, production and service, identification and traceability and calibration,

**Measurement, analysis and improvement** outlines how the organization determines customer satisfaction, internal audits, process monitoring, nonconforming product control, continual improvement activities and corrective/preventive actions.

Certification does not guarantee quality but it does reduce the risk of defects or customer dissatisfaction. ISO 9001 is considered the *baseline* of your business system. Other tools and methods such as Lean Six Sigma are then deployed to optimize your business.

