Quality Management Systems

Introduction

An organisation will benefit from establishing an effective quality management system (QMS). The cornerstone of a quality organisation is the concept of the customer and supplier working together for their mutual benefit. For this to become effective, the customer-supplier interfaces must extend into, and outside of, the organisation, beyond the immediate customers and suppliers.

A QMS can be defined as:

"A set of co-ordinated activities to direct and control an organisation in order to continually improve the effectiveness and efficiency of its performance."

These activities interact and are affected by being in the system, so the isolation and study of each one in detail will not necessarily lead to an understanding of the system as a whole. The main thrust of a QMS is in defining the processes, which will result in the production of quality products and services, rather than in detecting defective products or services after they have been produced.

The benefits of a QMS

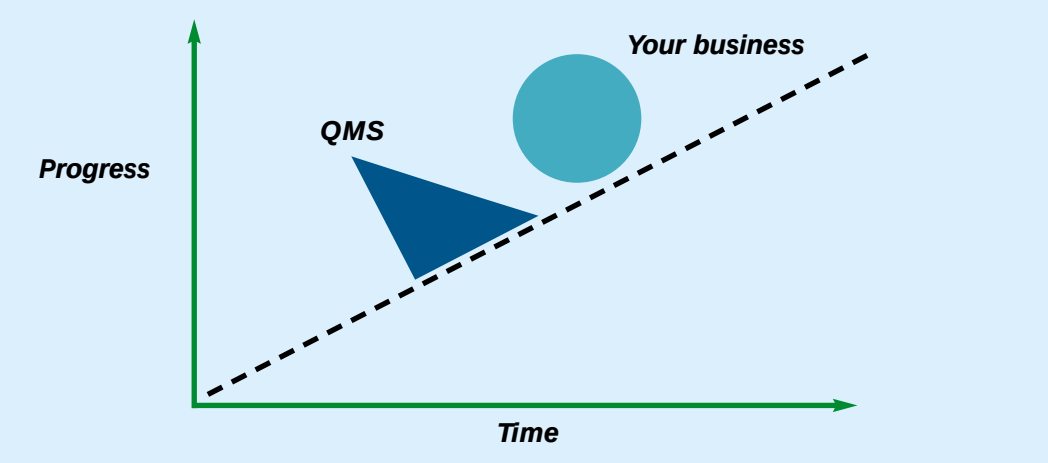
A fully documented QMS will ensure that two important requirements are met:

- The customers' requirements – confidence in the ability of the organisation to deliver the desired product and service consistently meeting their needs and expectations.
- The organisation's requirements – both internally and externally, and at an optimum cost with efficient use of the available resources – materials, human, technology and information.

These requirements can only be truly met if objective evidence is provided, in the form of information and data, to support the system activities, from the ultimate supplier to the ultimate customer.

A QMS enables an organisation to achieve the goals and objectives set out in its policy and strategy. It provides consistency and satisfaction in terms of methods, materials, equipment, etc, and interacts with all activities of the organisation, beginning with the identification of customer requirements and ending with their satisfaction, at every transaction interface.

It can be envisaged as a "wedge" that both holds the gains achieved along the quality journey, and prevents good practices from slipping:



Management systems are needed in all areas of activity, whether large or small businesses, manufacturing, service or public sector. A good QMS will:

- Set direction and meet customers' expectations
- Improve process control
- Reduce wastage
- Lower costs
- Increase market share
- Facilitate training
- Involve staff
- Raise morale

In a survey conducted by the Defence Evaluation Research Agency (DERA), ca.96% of respondents said they believed their system contributed to meeting the business goals. However, ca.72% responded that their organisation did not measure this contribution.

International Organization for Standardization (ISO)

ISO is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is carried out through ISO technical committees, in liaison with international organisations, governmental and non-governmental bodies. ISO's most recent family of standards for quality management systems are currently in their final draft (FDIS) form, and comprises:

- **ISO/FDIS 9000:2000 - Quality management systems – Fundamentals and vocabulary**
- **ISO/FDIS 9001:2000 - Quality management systems – Requirements**
- **ISO/FDIS 9004:2000 – Guidelines for performance improvement**

It is expected that they will be issued as an ISO in December 2000 or January 2001. If these vary from the FDIS version, changes will be made to this website.

They are built around business processes, with a strong emphasis on improvement and a focus on meeting the needs of customers. The new standards originated from a regular six year review and are intended to be generic and adaptable to all kinds of organisations.

The ISO 9002 and ISO 9003 are to be discontinued (but can still be used by those organisations certified against them during the three year transition period), and ISO 9001and ISO 9004 are designed to be used together, but can be used independently.

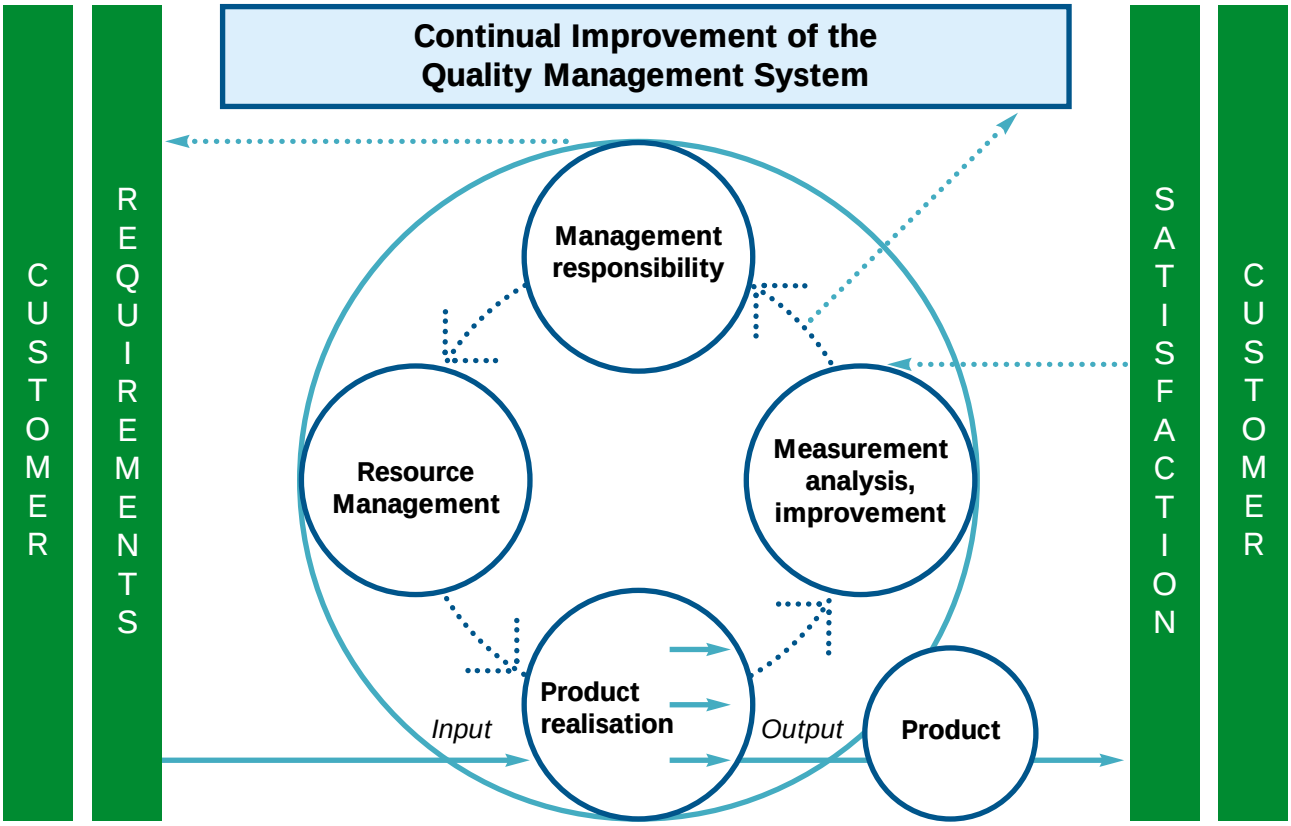
The ISO Series can form the means by which a holistic management system can be implemented, into which quality, health and safety and environmental responsibility can be integrated, with the audits carried out either separately or in combination.

The ISO Standard is also now more closely aligned with the requirements of the EFQM Excellence Model®.

ISO 9001

ISO 9001 specifies the requirements for a QMS that may be used by organisations for internal application, certification or contractual purposes.

The process approach is shown in the conceptual model from the ISO 9001 Standard, recognising that customers play a significant role in defining requirements as inputs, and monitoring of customer satisfaction is necessary to evaluate and validate whether customer requirements have been met.



The major clauses and sub-clause are:

- **Scope**
- **Normative reference**
- **Terms and definitions**
- **Quality management system**
  - General requirements
  - Documentation requirements
- **Management responsibility**
  - Management commitment
  - Customer focus
  - Quality policy
  - Planning
  - Responsibility, authority and communication
  - Management review
- **Resource management**
  - Provision of resources
  - Human resources
  - Infrastructure
  - Work environment

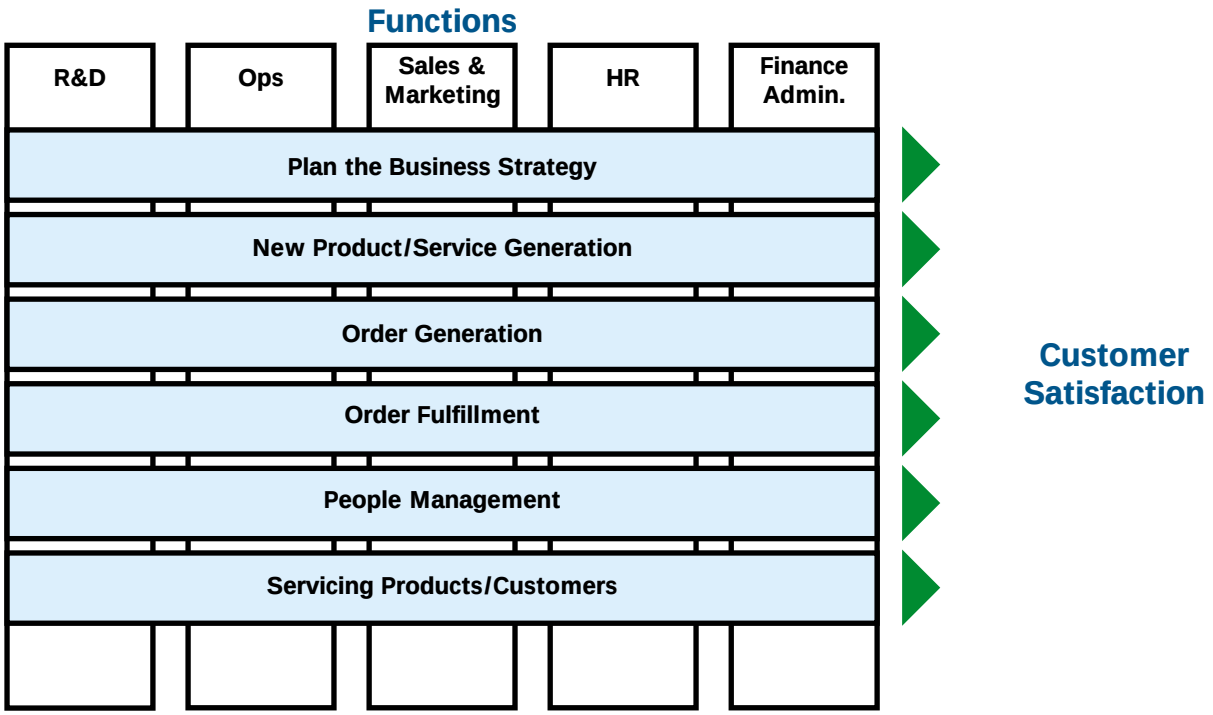
- **Product realisation**
  - Planning of product realisation
  - Customer-related processes
  - Design and/or development
  - Purchasing
  - Production and service operations
  - Control of measuring and monitoring devices

- **Measurement, analysis and improvement**
  - General
  - Planning
  - Monitoring and measurement
  - Control of non-conforming product
  - Analysis of data
  - Improvement

The management system requirements under these clauses are specified in more detail in the ISO 9001 Standard.

Setting up a QMS

As illustrated in the Process section, for organisations to function effectively, they have to identify and manage numerous interlinked, cross-functional processes, always ensuring customer satisfaction is the target that is achieved. The schematic illustrates this concept:



The adoption of a QMS needs to be a strategic decision of an organisation, and is influenced by varying needs, objectives, the products/services provided, the processes employed and the size and structure of the organisation. A QMS must ensure that the products/services conform to customer needs and expectations, and the objectives of the organisation. Issues to be considered when setting up a QMS include its:

- Design
- Build
- Control
- Deployment
- Measurement
- Review
- Improvement

Taking each of these in turn:

Design and **build** includes the structure of the quality management system, the process and its implementation. It's design must be led by senior managers to suit the needs of the organisation, and this is ideally done using a framework to lead the thinking. Design of the QMS should come from determining the organisation's core processes and well-defined goals and strategies, and be linked to the needs of one or more stakeholders.

The process for designing and building the QMS must also be clear, with the quality function playing a key role, but involvement and buy-in to the system must also come from all other functions.

Deployment and implementation is best achieved using process packages, where each core process is broken down into sub-processes, and described by a combination of documentation, education, training, tools, systems and metrics. Electronic deployment via Intranets is increasingly being used.

Control of the QMS will depend on the size and complexity of the organisation. ISO is a site-based system, and local audits and reviews are essential even if these are supplemented by central reviews. Local control, where possible, is effective, and good practice is found where key stakeholders are documented within the process and where the process owner is allowed to control all of the process. Ideally, process owners/operators are involved in writing procedures.

Measurement is carried out to determine the effectiveness and efficiency of each process towards attaining its objectives. It should include the contribution of the QMS to the organisation's goals; this could be achieved by measuring the following:

- Policy definition completeness
- Coverage of business
- Reflection of policies
- Deployment
- Usage
- Whether staff find the QMS helpful in their work
- Speed of change of the QMS
- Relevance of QMS architecture to the job in hand

A form of scorecard deployed through the organisation down to individual objective level can be employed, and the setting of targets at all levels is vital.

Review of the effectiveness, efficiency and capability of a QMS is vital, and the outcome of these reviews should be communicated to all employees. Reviewing and monitoring should be conducted whether or not improvement activities have achieved their expected outcomes.

Improvement should follow as a result of the review process, with the aim of seeking internal best practice. It is part of the overall improvement activities and an integral part of managing change within the organisation.

ISO 9000 contains eight quality management principles, upon which to base an efficient, effective and adaptable QMS. They are applicable throughout industry, commerce and the service sectors:

- Customer focus
- Leadership
- Involving people
- Process approach
- Systems approach
- Continual improvement
- Factual decision making
- Mutually beneficial supplier relationships

Taking each one in turn, they are explained more fully as:

An effective QMS must ensure that the organisation has a strong **Customer Focus**. Customer needs and expectations must be determined and converted into product requirements.

Top management have to demonstrate **Leadership**. Providing unity of purpose through an appropriate quality policy, ensuring that measurable objectives are established, and demonstrating that they are fully committed to developing, sustaining and improving the QMS.

Managers must ensure that there is **Involvement of People** at all levels in the organisation. This includes ensuring that there is an awareness of the importance of meeting customer requirements and responsibilities in doing this, and people are competent, on the basis of appropriate training and experience.

An effective QMS must be a strategic tool designed to deliver business objectives, and must have, at its core, a **Process Approach**, with each process transforming one or more inputs to create an output of value to the customer. The key business processes may be supported by procedures and work instructions in those cases where it is judged necessary to rigidly define what rules are to be followed when undertaking a task. Most organisations will have core business processes that define those activities that directly add value to the product or service for the external customer, and supporting processes that are required to maintain the effectiveness of the core processes.

The understanding of the many interrelationships between these processes demands that a **Systems Approach** to management is adopted. The processes must be thoroughly understood and managed so that the most efficient use is made of available resources, to ensure that the needs of all the stakeholders – customers, employees, shareholders and the community - are met.

Customer satisfaction is a constantly moving entity depending on changes in technology and the market place, so an effective QMS must be in a state of **Continual Improvement**. For this to be achieved, attention needs to be given to both the voice of the customer - through complaint analysis, opinion surveys and regular contacts – and the voice of the processes – through measurement, monitoring and analysis of both process and product data. This will result in **Factual Decision Making**.

Each organisation is itself only a link in the chain of a larger raw material process, and for the long term needs of the community and the organisation there needs to be **Mutually Beneficial Supplier Relationships**.

Audits, reviews and assessments

A good QMS will not function or improve without adequate audits and reviews.

Audits are carried out to ensure that actual methods are adhering to the documented procedures, whilst system reviews should be carried out periodically and systematically, to ensure the system achieves the required effect.

There should be a schedule for carrying out audits, with different activities possibly requiring different frequencies. An audit should not be conducted just with the aim of revealing defects or irregularities – they are for establishing the facts rather than finding faults. Audits do indicate necessary improvement and corrective actions, but must also determine if processes are effective and that responsibilities have been correctly assigned. The emphasis on process improvement and enhancing customer satisfaction in the revised standard will require a more thoughtful approach to auditing.

The generic steps involved in an audit are:

- **Initiation**
  - Scope
  - Frequency
- **Preparation**
  - Review of documentation
  - The programme
  - Working documents
- **Execution**
  - Opening meeting
  - Examination and evaluation
  - Collecting evidence
  - Observations
  - Close the meeting with the auditee
- **Report**
  - Preparation
  - Content
  - Distribution
- **Completion**
  - Report
  - Submission
  - Retention

A quality management system **review** should take place, possibly once a year, which should cover:

- Results of audits
- Customer feedback
- Process and product conformity
- Status of preventative and corrective actions
- Follow up actions from previous management reviews
- Changes that could effect the QMS
- Recommendations for improvements

Outputs should include:

- Improvements to the QMS and processes
- Improvements of a product related to customer requirements
- Resource needs

In addition, the procedures for conducting audits and reviews and the results from them should be documented, and also be subject to review. Internal system audits and reviews should be positive and conducted as part of the preventative strategy, and not as a matter of expediency resulting from problems.

The **assessment** of a quality system against a standard or set of requirements by internal audit and review is known as a ***first-party*** assessment or approval scheme. If an external customer makes the assessment of a supplier, against either its own, or a national or international, standard, a ***second-party*** scheme is in operation. The assessment by an independent organisation, not connected with any contract between the customer and supplier, but acceptable to them both, is an ***independent third-party*** assessment scheme.

The latter usually results in some form of certification or registration by the assessment body.

For third-party certification schemes to be of value they need to be backed by accreditation. In the U.K., the United Kingdom Accreditation Service (UKAS) is recognised by the Government as the sole national accreditation body for this purpose. UKAS accredits certification bodies by evaluating their competence against international standards.

An advantage of third-party certification, when backed by accreditation, is the assurance that it provides to customers that obviates the requirements for their own detailed checks but in addition it enables the certified organization to use the renowned national accreditation mark to denote this assurance, thus improving its competitiveness. Companies using the accredited certification bodies can also be included in the Stationery Office's publication which lists quality assured companies, the QA Register.

All managers, not just the staff in the "quality department", need to be fully committed to operating an effective quality management system for all the people within the organisation. The system must be planned to be effective and achieve its objectives in an uncomplicated way. It should also not be static, but be flexible, to enable constant seeking of improvements.