16) QUALITY MANAGEMENT SYSTEMS

INTRODUCTION

The aim of this paper is to give a brief introduction to the idea of a quality management system and specifically in ISO 9001:2000: Quality Management System.

When we talk about a system, the earliest documented we come across in history is the “Egyptian Book of the Dead” which describes the internment of the Pharaohs. It took so long for the management science to come up with a similar, certainly more sophisticated, documented system when again a need for it has arisen. The need for a quality assurance system that would ensure work “right first time”, be reliable and be cost effective came ironically from the military people for to fight more effectively. The first attempt to standardise quality system was the USA Military Standards MIL-Q-9858 (Quality System Specification).

In 1987, The International Organisation for Standardisation (ISO), drawing upon many national inputs, produced an international quality system standard mainly for manufacture (ISO 9000 series). In 1994 the ISO 9000 series were revised and re-issued, to focus more on the prevention aspects of quality assurance and to include service also as a product and placed the responsibility for quality where it rightly belongs - with executive management.

For the second revision of the standard, which were already planned to be implemented in the earlier revision, a more holistic approach was taken and a “system” model was drawn on processes.

Technical Committee 176, quality management and quality assurance is responsible for ISO 9000, Sub Committees are responsible for the drafts:

- SC1- ISO 9000, concepts and terminology
- SC2- ISO 9001 and ISO 9004, quality standards
- SC3- is working with an Environmental Technical Committee TC207 and
- SC2 to develop ISO 19011 as an auditing standard to replace ISO10011 and ISO 14010/11/12.

From the early 1998 (first committee draft was CD1 of July 1998) until the final issue in December 2000, a full 3 years was spent to design the system, a system, which directs and controls the organisation with regard to quality.

THE BENEFITS OF A QMS

Main aim is to identify and meet the needs and expectations of its customers and legal requirements. To do this in an effective manner, organisation must achieve, maintain, and improve overall organisational performance. Overall performance of the organisation may impact on:

- customer loyalty
- repeat business
- operational results such as revenue and market share increase
- flexible and fast responses to market opportunities
- alignment of processes which will best achieve desired results

Ability to create value for both the organisation and its suppliers by optimisation of costs and resources as well as flexibility and speed of agreed joint responses to changing markets can be built upon an effective system. That is to say the efficiency can only be achieved on top of effectiveness.

THE PHILOSOPHY OF QMS

In order to lead and operate an organisation successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties.

Managing an organisation encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified as the framework towards improved performance of an organisation. Aimed at helping organisations to achieve sustained success, they are:

Customer focus

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

Leadership

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

Involvement of people

People at all levels are the essence of an organisation and their full involvement enables their abilities to be used for the organisation’s main benefit

Process Approach

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

System approach to management

Identifying, understanding and managing interrelated processes as a system contributes to the organisation’s effectiveness and efficiency in achieving its objectives.
Continual improvement

Continual improvement of the organisation’s overall performance should be a permanent objective of the organisation.

Factual approach to decision making

Effective decisions are based on the analysis of data and information

Mutually beneficial supplier relationships

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

RELATED TERMINOLOGY

Quality; Degree to which, a set of inherent characteristics fulfils requirements. (Quality now permits logical use of a qualifying term “poor quality”, “good quality” or “excellent quality”)

Quality Improvement; Part of Quality management focused on increasing the ability to fulfil quality requirements, these requirements can be related to any aspect such as effectiveness, efficiency or traceability.

Effectiveness; Measure of the extent to which planned activities are realised and planned results achieved.

Efficiency; Relationship between results achieved and resources used.

Information; Meaningful data

Process; Set of interrelated or interacting activities which transforms inputs into outputs

Product; The result of a process

THE ISO 9000 STANDARD SERIES

The new series of the standard has been conglomerated into 4 main standards from around 20 standards of the ’94 revision. These are:

- ISO 19011 – Guidelines on Quality and Environmental Management Systems Auditing

This standard acts as an introduction to the series, setting and the principles. It covers terms and definitions (replaces ISO 8402) and explains the fundamental of quality management systems and their elements. It outlines the ‘process approach’ and introduces a generic model.

ISO 9004: 2000 – QUALITY MANAGEMENT SYSTEMS – GUIDANCE FOR PERFORMANCE IMPROVEMENTS

This standard goes beyond ISO 9001 requirements and provides guidelines for improvement activities. It is structured in parallel with ISO 9001 and provides a generic guideline for self-assessment and a methodology for improvement (Annex B) It is strictly not intended for use as a guidance document for implementing ISO 9001: 2000


This standard states five major requirements of quality management systems:

- **Quality Management System** including general and documentation requirements
- **Management Responsibilities** including responsibilities and commitment of ‘Top Management’
- **Resource Management** including allocation of resources and competence of personnel.
- **Product Realisation** including, customer related processes, design, purchasing, production, validation of processes and products, identification, traceability and control of monitoring and measuring devices.
- **Measurement, Analysis and Improvement** includes, customer satisfaction, internal audit, monitoring and measurement of processes and products, control of nonconforming product, analysis of data and improvement (including corrective and preventive action)

The key concepts of the ISO 9001; 2000 revolve around the 8 quality principles discussed previously. Within each of the standard’s requirements these principles lies as related concepts. (e.g. Customer focus, understanding requirements and undertaking some form of customer review process, understanding customer perception of actions taken in response to complaints.)

The Scope of ISO 9001: 2000 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

**PROCESS APPROACH**

Any activity that receives inputs and converts them to outputs with resources and controls can be considered as a process. For effective management of the processes we must:
- Identify and manage interlinked processes.
- Understand that output of one process is input to the next process.
- Do systematic management of processes.

ISO 9001: 1994 used “processes” only for “production, installation and servicing” under clause 4.9-Process Control. Where as 9001:2000 recognises that all activities of the QMS can be viewed as interrelated processes. Systems therefore may be implemented by “process” rather than “standard clause/procedures” and effective improvements can only be done if processes are defined and measured.

The key elements of a process are “inputs”, “resources” and “controls” in order to produce “outputs”.

If we take a Business as a process, then the process (the business) requires inputs (information, materials), resources (people, equipment, space) and controls (QMS) to produce outputs (products and/or services).

SYSTEM APPROACH

Clause 3.3 of ISO 9000: 2000 defines an approach for maintaining and improving an existing quality management system or developing and implementing a new quality management system as consisting of several steps including:

- Determine needs and expectations of the customer and other interested parties
- Establish the quality policy and quality objectives of the organisation
- Determine the processes and responsibilities necessary to attain the quality objectives
- Determine and provide the resources necessary to attain the quality objectives
- Establish the methods to measure the effectiveness and efficiency of each process
- Apply these measures to determine the effectiveness and efficiency of each process
- Determine means of preventing nonconformities and eliminating their causes
- Establish and apply a process for continual improvement of the quality management system
- Assess the results against expected outcomes
- Review the improvement activities to determine follow up action

CONTINUAL IMPROVEMENT

The requirement to plan for continual improvement is widely held to be the most significant change in the year 2000 version of ISO 9001. Under the existing standard, improvement of the quality management system should have sprung from the corrective and preventive action procedures.

What is new is the requirement to include continual improvement in planning activity, and the introduction of supporting elements throughout the standard. These include:

- the requirement of the quality management system to measure, monitor and analyse processes and implement actions to achieve improvement
- management commitment to continual improvement expressed in the quality policy
- quality objectives, measurable and consistent with continual improvement
• actions related to improvement as an output from management review

From these points it is clear that continual improvement relies on the commitment and support of top management.

Improvement can apply to any or all parts of the system, including the core realization processes, but not ignoring supporting processes and activities. It can be thus related to any of clauses 5-8 of the standard (and through them to clause 4), but also to other business issues, for example those benefiting other interested parties.

**FINAL WORDS**

An organisation adopting the above approach creates confidence in the capability of its processes, and the quality of its products, and provides a basis for continual improvement. This leads to increased satisfaction of customers and other interested parties and to the success of the organisation.

Its up to the management to decide to continue to grow an effective and efficient company, a learning organization, which manages the change and innovation to create the future; or a stagnant structure, which will only last until the first efforts of the nearest competitor. This is even true for the countries.