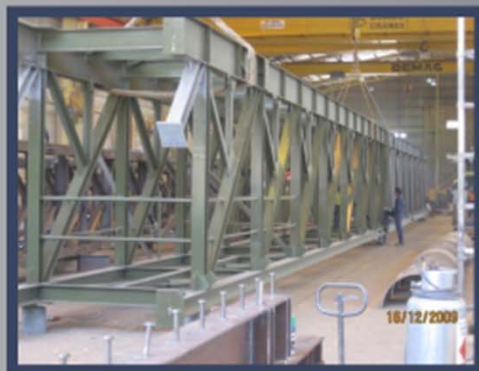


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ISO 9001:2008 Quality Management

Overview

ISO 9001 is an internationally recognised Integrated Management System. Many production and service related entities have invested in ISO 9001 in order to establish, document and continually improve systems and operating procedures through out their businesses.



ISO 9001:2008 Quality Management System

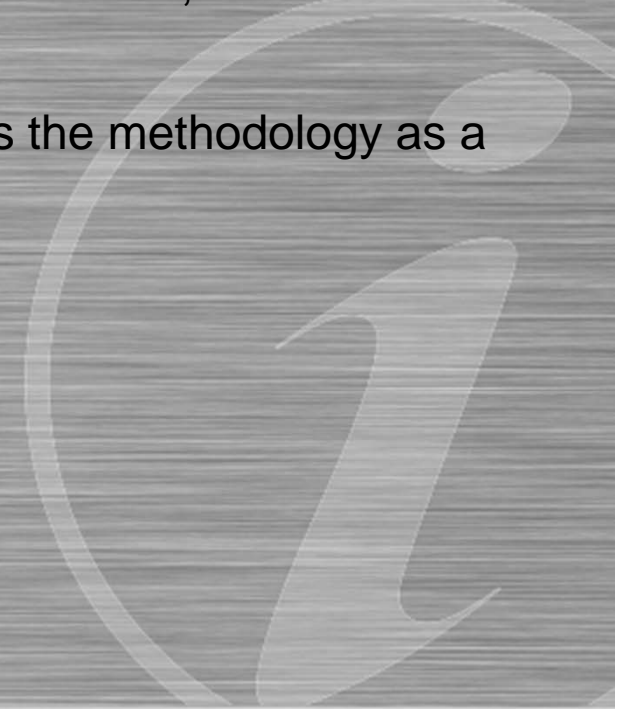
Overview

Dr. W. Deming is a name synonymous with efficiency and effectiveness.

He is quoted as saying “If it moves measure it” and without statistical methods, attempts to improve a process are hit and miss, with results which usually make matters worse.

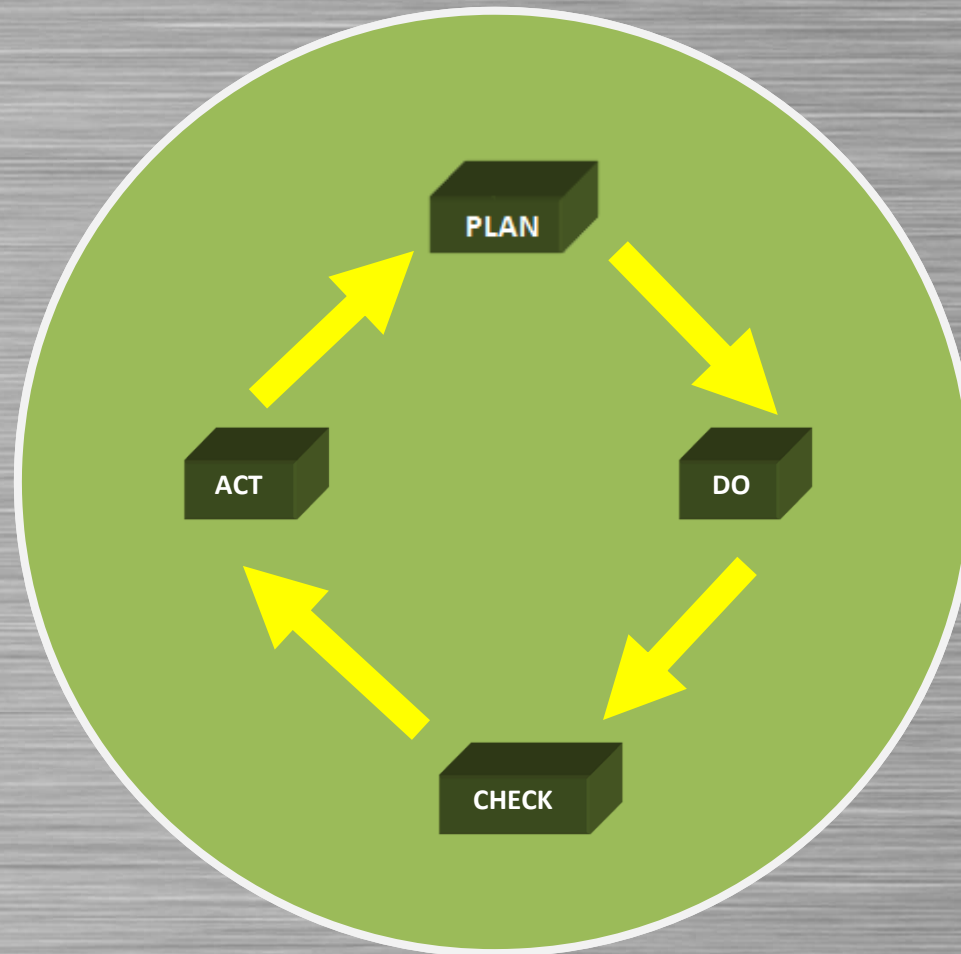
The way Deming tackled productivity has now become one of the classics, and is known as the Deming Cycle and/or PDCA cycle.

Use of the Deming Cycle is so widespread that ISO 9001 includes the methodology as a means of process improvement. Here is the Deming Cycle:



ISO 9001:2008 Quality Management System

The Deming Cycle



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Overview

ISO 9001:2008 is the current international standard on quality assurance, applicable to production and service. The 2008 version represents a considerable advance on the earlier 1994 version which set down 20 clauses that organisations seeking accreditation had to demonstrate.

ISO 9001 can be used by an organisation to both demonstrate its capability and to assess its ability to meet customer requirements.

ISO 9001 sets the quality system standards, not the product standards. Quality is defined as the “degree to which a set of inherent characteristics fulfils requirements.”

The 2008 version is based on eight Quality Management Principles that are an excellent guide to modern thinking on quality.

The principles are:

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Overview

- **Customer Focused**

As businesses and other organisations depend on their customers or clients, they need to learn about their needs and expectations, and deliver products / services that meet or exceed them.



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Overview

- **Leadership**

It is up to the top management of an organisation to establish its mission and objectives, to effectively communicate them, and to provide both the resources and suitable working environment for them to be achieved.



ISO 9001:2008 Quality Management System

Overview

- **Involvement of People.**

An organisation needs to ensure that its people are motivated, committed to, and actively participating in achieving its objectives. This requires the desire, communication skills and effort on the part of top management to get the message across. When carried out successfully, it can lead to greater realisation of the potential of the organisation's human resources.



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Overview

- **Process Approach.**

Modern management theory suggests that that objectives are best achieved when actions and the resources needed for them are managed as a 'process'.

The process approach means that activities are considered in terms of what inputs are provided, what outputs are expected, what resources are needed, what risks are there, what are the objectives, what method is to be used, and so on. All these factors are considered and managed together. Consideration is also given to the relationship between the various processes that take place in the organisation.

Taking the process approach typically involves 'flow charting' activities or recording them into a 'Process plan'

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Overview

- **Systems Approach.**

This principle suggests that an organisation is more effective and efficient when its key processes are considered together as a system.

The systems approach involves looking at the bigger picture, and managing an organisation systematically. Each process needs to interact and be managed in harmony with the others. Consideration is given to the relationship between the various processes - how the performance of one can affect another, and how they all fit into the overall scheme of things. The output of one process may be the input to the next. This introduces the concept of the 'internal customer' - where those responsible for one process need to be mindful of the needs of their colleagues. There needs to be a minimising of any barriers or contrasting aims between business units. Eventually of course, the organisation's output is to its external customers. Overall systems are often illustrated by a 'process map' - which is really a high-level flow chart.

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Overview

- **Continual Improvement.**

Improvements in methods, performance and outcomes should be sought on a continuous basis. To do this requires a certain culture to be established within the organisation - where people don't sit on their laurels but are always on the lookout for 'a better way'. Suitable mechanisms also need to be provided for people to communicate their ideas.



ISO 9001:2008 Quality Management System

Overview

- **Fact-based approach to decision making.**

This principle calls for experience to be complemented by factual analysis. The theory being that decisions are most likely to be correct if they have some basis on accurate and relevant data. To adhere to this principle, it would be necessary to obtain relevant information, ensure that it is accurate, and analyse it methodically.



ISO 9001:2008 Quality Management System

Overview

- **Mutually beneficial supplier relationships.**

To some degree, this principle is the other side of the coin to principle No. 1 - customer focus. Here, your organisation is the customer, and you are giving those that supply you a clear understanding of your needs and expectations. This principle also appears to seek a balance between short-term gains (perhaps such as obtaining the lowest price for an item at any given time) and developing long-term relationships with key vendors.

In any individual case, the application of these 8 principles would depend on the size and nature of an organisation, its industry sector and the issues and challenges it faces.

The theory is that taking such an approach will enhance an organisation's efficiency and effectiveness in achieving its objectives.

ISO 9001:2008 Quality Management System

Overview

- **The New Standard.**

The new standard has core sections which are broadly similar to the Deming PDCA cycle.

Management must plan the system in relation to customers, the resources must be provided, the activities carried out, and then measured, analysed and improved.

The standard provides fairly specific guidelines and advice on each. In the overview below, some important points are highlighted which are useful to gain an impression of what ***Integrated Quality*** involves.

ISO 9001:2008 Quality Management System

Overview

- **General Requirements.**

Like the previous version, the phrase “say what you do and do what you say” still applies. You make up the rules for your own organisation following the guidelines. Then you are expected to follow them and be audited upon them.

The organisation must identify the necessary processes, determine criteria, ensure the availability of resources, monitor and measure, and implement to achieve results and continual improvement. *(In short, PDCA).*

ISO 9001:2008 Quality Management System

Overview

- **Management Responsibility.**

Management must establish the quality policy, the policy must be communicated, and management must demonstrate and give evidence of its commitment. Senior management must ensure that customer needs and expectations are determined, and ensure that the organisation is able to fulfil the requirements.

Processes must be identified. A quality management system must be established, documented, maintained, and improved. A management representative must promote an awareness of customer requirements. A review process must take place to ensure that the quality system remains effective.

ISO 9001:2008 Quality Management System

Overview

- **Resource Management.**

This covers human resources, facilities, and the work environment. Management must determine and provide the necessary resources and facilities to implement the system and to address customer satisfaction. Records must be kept of experience, training, and qualifications. Ongoing training is an essential element and must be evaluated.

ISO 9001:2008 Quality Management System

Overview

- **Production and service provision (planning & realisation).**

This is a mini PCDA cycle within the broader quality system. The emphasis is on process. The steps of the process must be determined, say by flowcharts.

Customer requirements must be clearly understood and orders not accepted until there is the ability to meet the requirements. Communication with the customer must take place. The process must be designed, reviewed, verified, and measured, all in relation to the customer.

ISO requires a system for suppliers to be identified, selected, communicated with, and evaluated. Then the entire process needs to be controlled by having acceptance criteria, work standards, capable processes, and procedures for release, delivery and service. ISO also gives guidelines on traceability, customer property, preservation of product, process validation, and the control of measuring devices.

ISO 9001:2008 Quality Management System

Overview

- **Design and development. (if applicable).**
These requirements ensure that the process of design is planned and controlled. The organisation is expected to design the stages, review and validate, and clarify responsibilities.



ISO 9001:2008 Quality Management System

Overview

- **Purchasing, production and service provision.**
Purchased products must conform to requirements and suppliers must be chosen and evaluated in relation to criteria that must be established.
Production must be carried out under controlled conditions, including work standards, equipment, and monitoring and measurement. In short using standard operations and capable equipment.



ISO 9001:2008 Quality Management System

Overview

- **Measurement, analysis, improvement.**

Finally the system needs to be measured, monitored and controlled, and improved. Non-conformities need to be controlled. The new standard is more specific on improvement and on customer satisfaction which needs to be included in any performance measurement system. Processes and products need to be monitored. Importantly feedback needs to be given to Management Review, thereby closing the loop.

ISO 9001:2008 Quality Management System

Overview

ISO 9001 includes reduced requirements for documentation in comparison with the old standard. The organisation has greater freedom to specify its own documentation, but must nevertheless have documentation for the effective planning, operation and control of its processes. Six types of documentation are specifically required, for:

- ▶ control of documents,
- ▶ control of nonconforming products,
- ▶ corrective actions,
- ▶ preventive actions,
- ▶ control of records,
- ▶ internal quality audits.

Criticisms of the old standard cited its cost to implement, excessive “red tape”, its unsuitability for particular kinds of industry, and the possibility of management attention being diverted from real quality issues. On the positive side certification gives credibility, a reduction in the necessity for supplier audits, and may bring order to an undisciplined company. Hopefully the problems have been reduced, whilst benefits remain.

ISO 9001:2008 Quality Management System

Steps to Certification

- **Interpret ISO 9001**
in terms of its application and suitability to your business
- **Undertake a GAP analysis**
A Gap analysis is a tool that demonstrates the Gap between a Companies current systems/processes and the requirements stipulated in ISO 9001.
- **Prepare a “target” Program.**
Project plan (program) that will become a guide in terms of a scope of work and time lines for the development, implementation and certification of ISO 9001.
- **Explain the documentation methodology.**

ISO 9001:2008 Quality Management System

Steps to Certification

- **External audit and Certification.**

Once the system is fully implemented, a company can schedule the external audit and certification process.



ISO 9001:2008 Quality Management System Following Certification

- **Continuous Improvement and development.**
This is what over time will lift a company from ordinary to extraordinary, and is the real proven value in this management system!

