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ICON

QUALITY ASSURANCE

DEFINITION

Quality assurance (**QA**) is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering solutions or services to customers; whichISO 9000 defines as "part of quality management focused on providing confidence that quality requirements will be fulfilled". This defect prevention in quality assurance differs subtly from defect detection and rejection in quality control, and has been referred to as a *shift left* as it focuses on quality earlier in the process.

QA is applied to physical products in pre-production to verify what will be made meets specifications and requirements, and during manufacturing production runs by validating lot samples meet specified quality controls. QA is also applied to software to verify that features and functionality meet business objectives, and that code is relatively bug free prior to shipping or releasing new software products and versions.

Quality assurance comprises administrative and procedural activities implemented in a quality system so that requirements and goals for a product, service or activity will be fulfilled. It is the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention. This can be contrasted with quality control, which is focused on process output.

PRINCIPLES:

Two principles included in quality assurance are:

- "Fit for purpose" (the product should be suitable for the intended purpose); and "right first time" (mistakes should be eliminated). QA includes management of the quality of raw materials, assemblies, products and components, services related to production, and management, production and inspection processes.
- Suitable quality is determined by product users, clients or customers, not by society in general. It is not related to cost, and adjectives or descriptors such as "high" and "poor" are not applicable.
- For example, a low priced product may be viewed as having high quality because it is disposable, whereas another may be viewed as having poor quality because it is not disposable.

APPROACHES

Failure testing

A valuable process to perform on a whole consumer product is failure testing or stress testing. In mechanical terms this is the operation of a product until it fails, often under stresses such as increasing vibration, temperature, and humidity. This exposes many unanticipated weaknesses in a product, and the data is used to drive engineering and manufacturing process improvements. Often quite simple changes can dramatically improve product service, such as changing to mold-resistant paint or adding lock-washer placement to the training for new assembly personnel.

Statistical control

Statistical control is based on analyses of objective and subjective data. Many organizations use statistical process control as a tool in any quality improvement effort to track quality data. Any product can be statistically charted as long as they have a common cause variance or special cause variance to track.

Walter Shewart of Bell Telephone Laboratories recognized that when a product is made, data can be taken from scrutinized areas of a sample lot of the part and statistical variances are then analyzed and charted. Control can then be implemented on the part in the form of rework or

scrap, or control can be implemented on the process that made the part, ideally eliminating the defect before more parts can be made like it.

Total quality management

The quality of products is dependent upon that of the participating constituents,[9] some of which are sustainable and effectively controlled while others are not. The process(es) which are managed with QA pertain to Total Quality Management.

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Models and standards

ISO 17025 is an international standard that specifies the general requirements for the competence to carry out tests and or calibrations. There are 15 management requirements and 10 technical requirements. These requirements outline what a laboratory must do to become accredited. Management system refers to the organization's structure for managing its processes or activities that transform inputs of resources into a product or service which meets the organization's objectives, such as satisfying the customer's quality requirements, complying with regulations, or meeting environmental objectives.

The Capability Maturity Model Integration (CMMI) model is widely used to implement Process and Product Quality Assurance (PPQA) in an organization. The CMMI maturity levels can be divided into 5 steps, which a company can achieve by performing specific activities within the organization.

Company quality

During the 1980s, the concept of "company quality" with the focus on management and people came to the fore.It was realized that, if all departments approached quality with an open mind, success was possible if the management led the quality improvement process.

The company-wide quality approach places an emphasis on four aspects:-

1. Elements such as controls, job management, adequate processes, performance and integrity criteria and identification of records
2. Competence such as knowledge, skills, experiences, qualifications

3. Soft elements, such as personnel integrity, confidence, organizational culture, motivation, team spirit and quality relationships.
4. Infrastructure (as it enhances or limits functionality)

The quality of the outputs is at risk if any of these aspects is deficient.

QA is not limited to the manufacturing, and can be applied to any business or non-business activity, including: design, consulting, banking, insurance, computer software development, retailing, investment, transportation, education, and translation.

It comprises a quality improvement process, which is generic in the sense that it can be applied to any of these activities and it establishes a behavior pattern, which supports the achievement of quality.

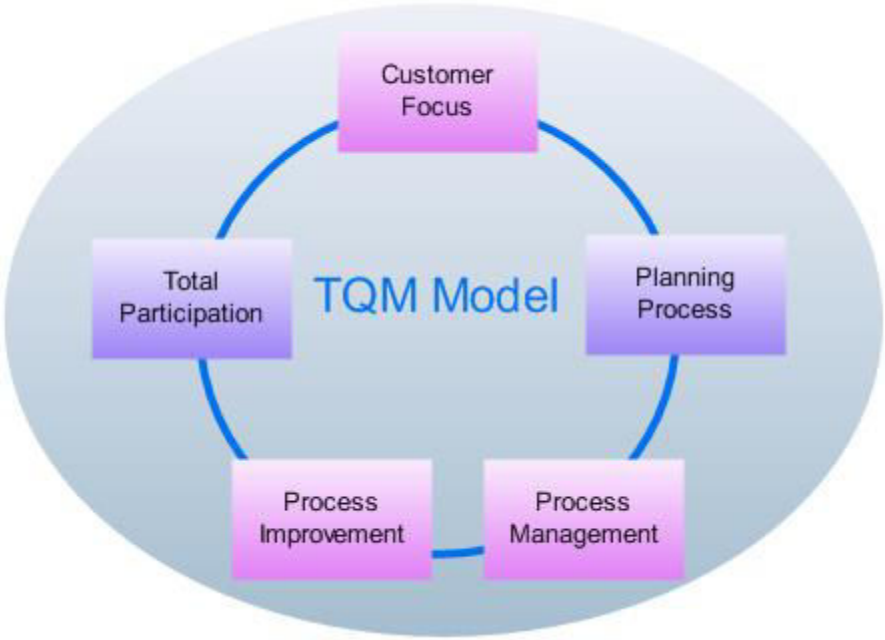
This in turn is supported by quality management practices which can include a number of business systems and which are usually specific to the activities of the business unit concerned.

In manufacturing and construction activities, these business practices can be equated to the models for quality assurance defined by the International Standards contained in theISO 9000 series and the specified Specifications for quality systems.

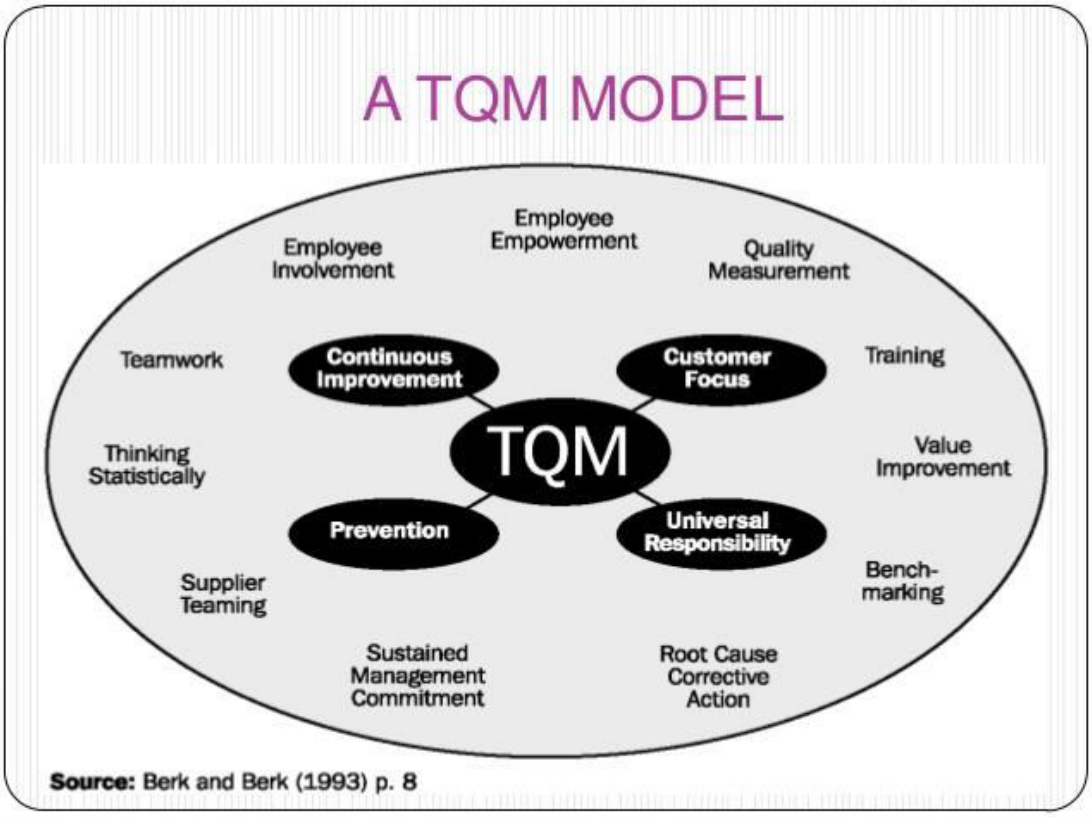
In the system of Company Quality, the work being carried out was shop floor inspection which did not reveal the major quality problems. This led to quality assurance or total quality control, which has come into being recently.

TOTAL QUALITY MANAGEMENT

Total quality management (**TQM**) consists of organization-wide efforts to install and make permanent a climate in which an organization continuously improves its ability to deliver high-quality products and services to customers. While there is no widely agreed-upon approach, TQM efforts typically draw heavily on the previously developed tools and techniques of quality control. TQM enjoyed widespread attention during the late 1980s and early 1990s before being overshadowed by ISO 9000, Lean manufacturing, and Six Sigma.


Customer Focus
Planning Process
Process Management
Process Improvement
Total Participation
TQM Model


Committment
Control
Culture
6 Cs of TQM
Customer Focus
Continous Improvement
Cooperation

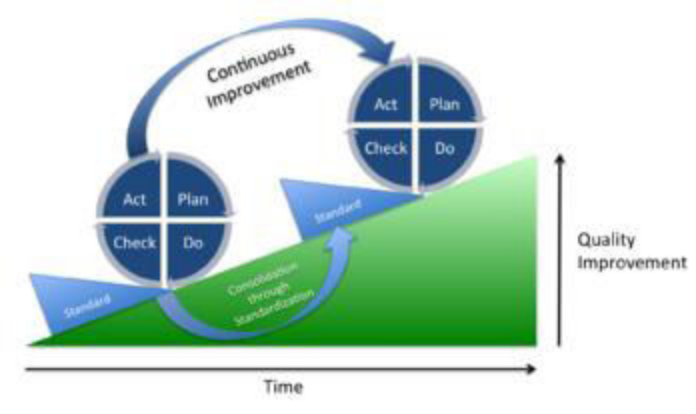


SCHEWART CYCLE:

PDCA (**plan–do–check–act** or **plan–do–check–adjust**) an iterative four-step management method used in business for the control and continuous improvement of processes and products. It is also known as the **Deming circle/cycle/wheel**, **Shewhart cycle**, **control circle/cycle**, or **plan–do–study–act** (**PDSA**). Another version of this PDCA cycle is OPDCA. The added "O" stands for observation or as some versions say "Grasp the current condition." This emphasis on observation and current condition has currency with Lean/Toyota Production System literature.

MEANING

The PDCA cycle



PLAN

Establish the objectives and processes necessary to deliver results in accordance with the expected output (the target or goals). By establishing output expectations, the completeness and accuracy of the spec is also a part of the targeted improvement. When possible start on a small scale to test possible effects.

DO

Implement the plan, execute the process, make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps.

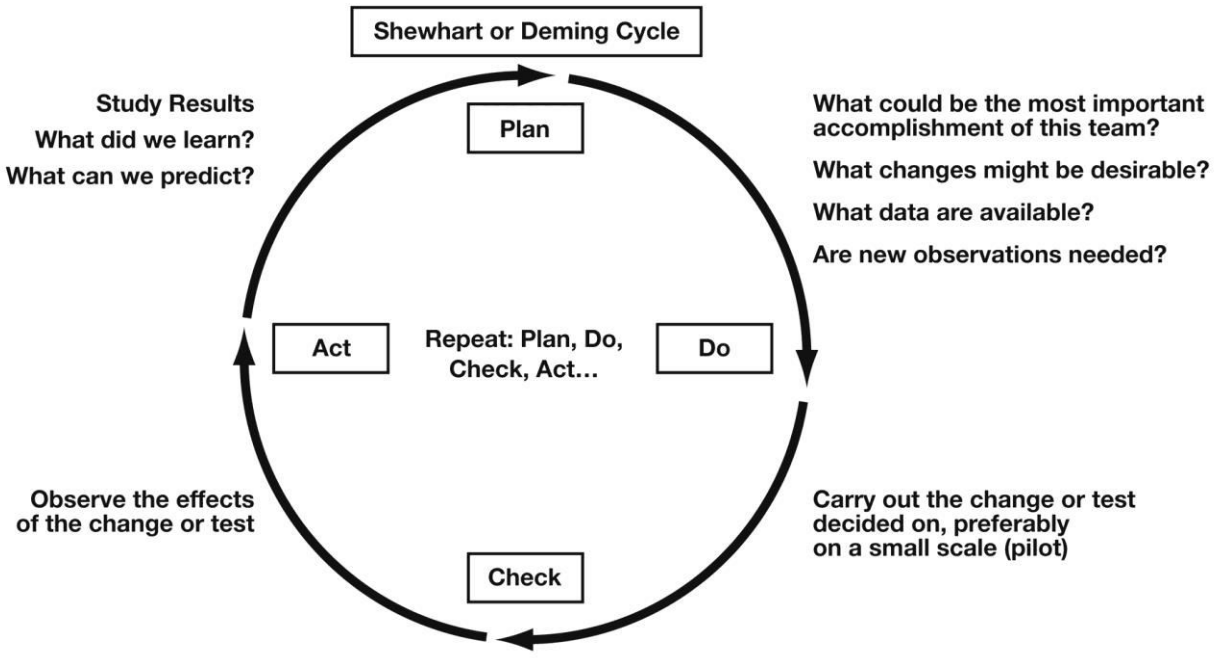
CHECK

Study the actual results (measured and collected in "DO" above) and compare against the expected results (targets or goals from the "PLAN") to ascertain any differences. Look for deviation in implementation from the plan and also look for the appropriateness and completeness of the plan to enable the execution, i.e., "Do". Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. Information is what you need for the next step "ACT".

ACT

If the CHECK shows that the PLAN that was implemented in DO is an improvement to the prior standard (baseline), then that becomes the new standard (baseline) for how the organization should ACT going forward (new standards are enACTed). If the CHECK shows that the PLAN that was implemented in DO is not an improvement, then the existing standard (baseline) will remain in place. In either case, if the CHECK showed something different than expected (whether better or worse), then there is some more learning to be done... and that will suggest potential future PDCA cycles. Note that some

who teach PDCA assert that the ACT involves making adjustments or corrective actions... but generally it would be counter to PDCA thinking to propose and decide upon alternative changes without using a proper PLAN phase, or to make them the new standard (baseline) without going through DO and CHECK steps.

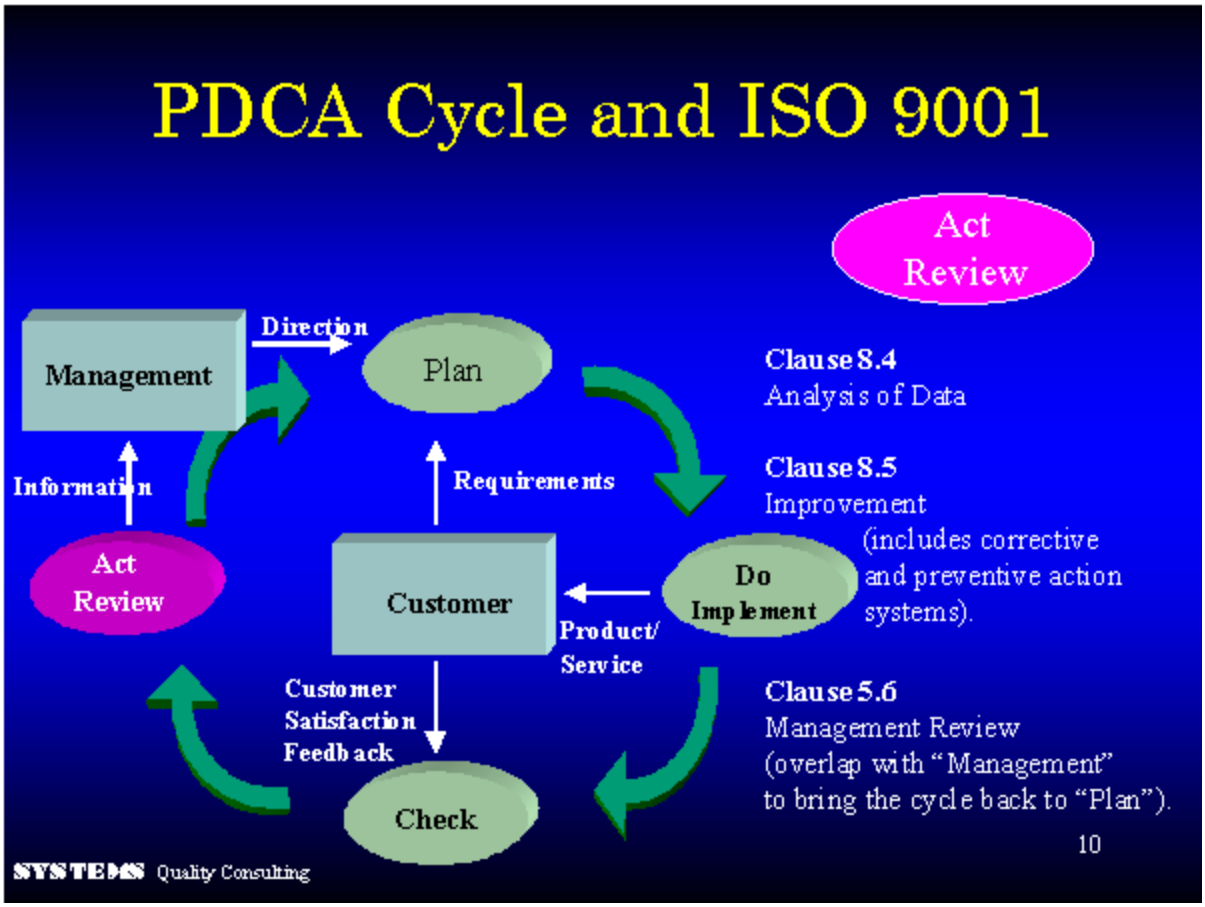


ISO CYCLE:

The **ISO/IEC 12207** standard establishes a process of lifecycle for software, including processes and activities applied during the acquisition and configuration of the services of the system. Each Process has a set of outcomes associated with it. There are 23 Processes, 95 Activities, 325 Tasks and 224 Outcomes (the new "ISO/IEC 12207:2008 Systems and software engineering – Software life cycle processes" defines 43 system and software processes).

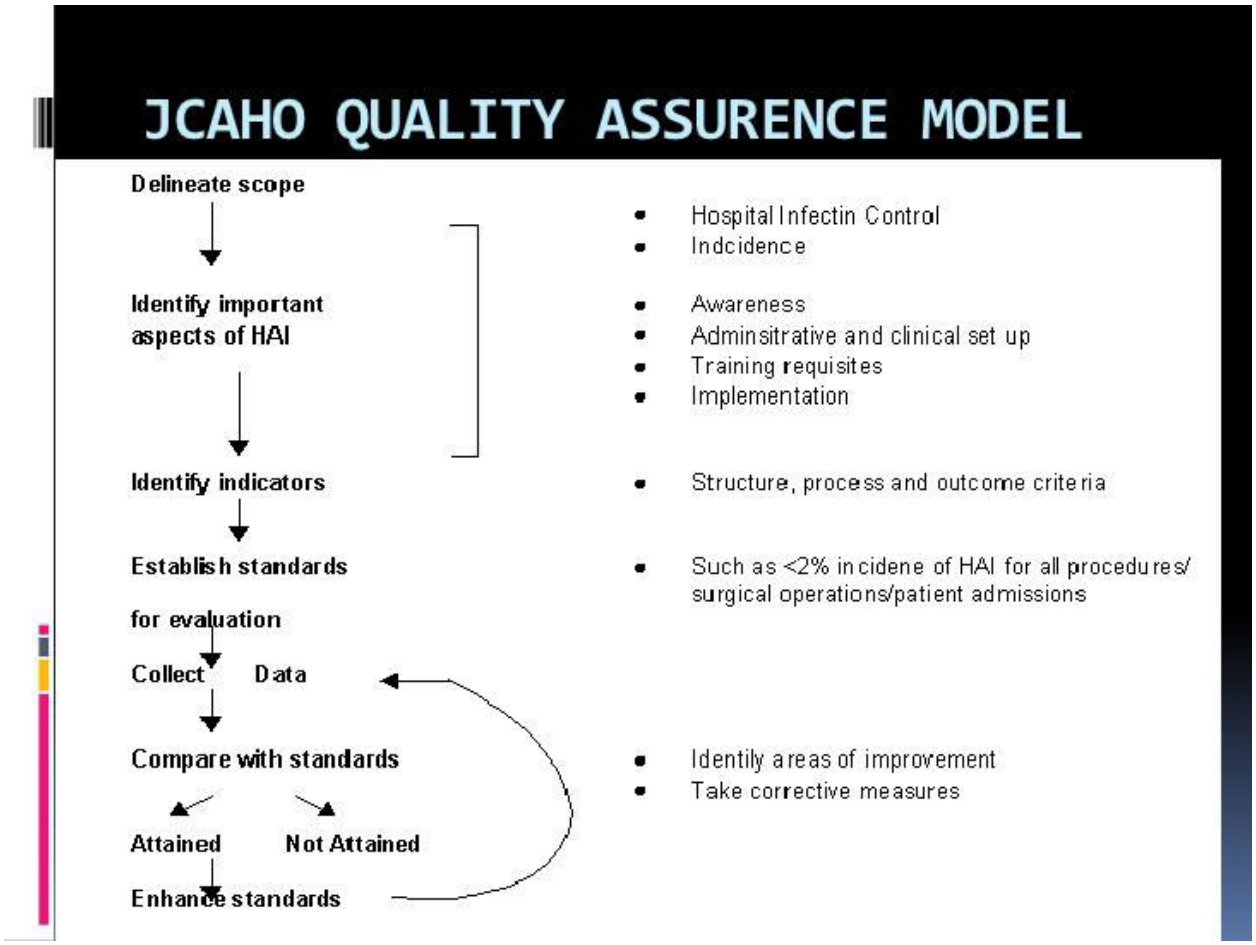
The standard has the main objective of supplying a common structure so that the buyers, suppliers, developers, maintainers, operators, managers and technicians involved with the software development use a common language. This common language is established in the form of well defined processes. The structure of the standard was intended to be conceived in a flexible, modular way so as to be adaptable to the necessities of whoever uses it. The standard is based on two basic principles: modularity and responsibility. Modularity means processes with

minimum coupling and maximum cohesion. Responsibility means to establish a responsibility for each process, facilitating the application of the standard in projects where many people can be legally involved.



JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO)

The Joint Commission (TJC) is a United States-based nonprofit tax-exempt 501(c) organization that accredits more than 20,000 health care organizations and programs in the United States. A majority of state governments recognize Joint Commission accreditation as a condition of licensure and the receipt of Medicaid reimbursement.



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