



Variability is the Enemy of Quality

Variation reduces quality, increases risk of defects

Quality Management Principles



serve as the underlying foundation for the ISO quality requirements



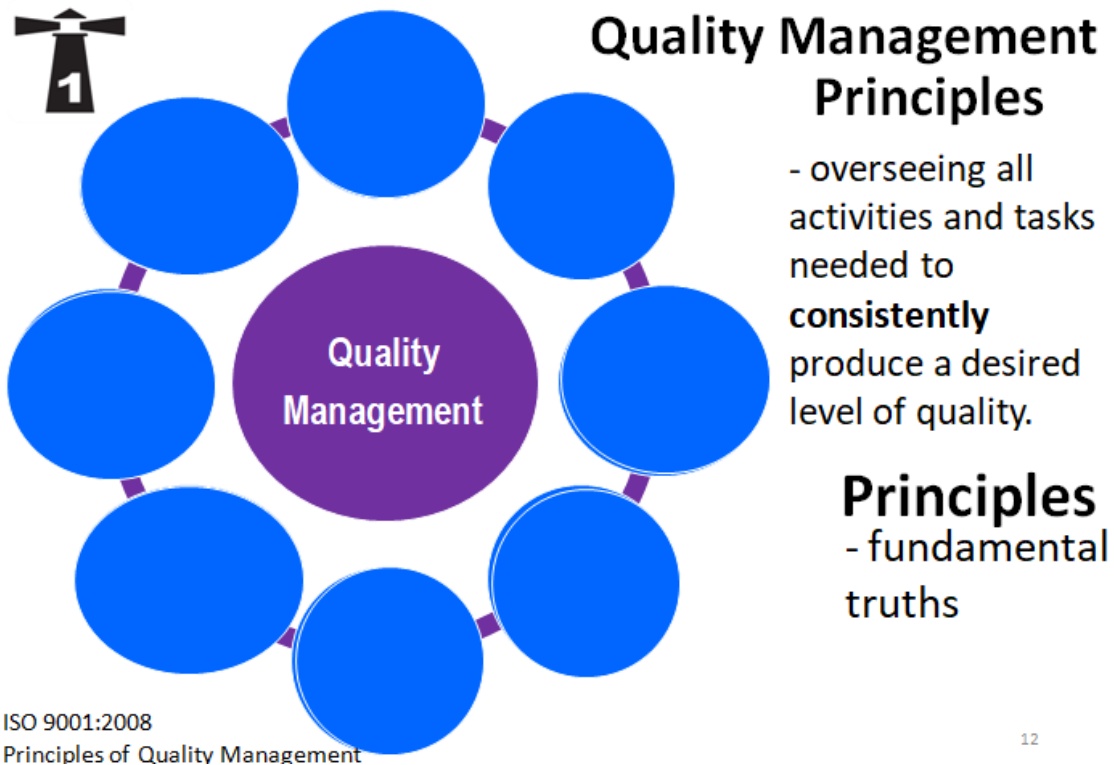
standardize management system practices that meet the ISO requirements.

The basis for continuous improving is in the managing of variation. Variation is the fluctuation of the output of a process. Every repeatable process exhibits variation. Improvement of any process is to reduce variation so that the process can consistently meet customer expectations.

Studying variation leads to managing it, as this will help to identify the source of a problem and to establish the action most likely to resolve it.

These principles form the conceptual foundation for the ISO quality management standards and serve as the basis for the Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP).

The central problem in management and in leadership...is failure to understand the information in variation. W. Edward Deming



ISO 9001:2015 – This standard provides the requirements for quality management systems.

There were 8 principles in the 2008 version of ISO9001. With the 2015 version, the *System Approach to Management* principle was removed. Therefore, the current version of the standard presents not 8, but 7 principles. Ironically, these principles are presented under the title of the standard - Quality Management **SYSTEMS**. Apparently, a system approach is still essential.

A principle is a fundamental truth or law and therefore quality management principles are the fundamental truth or laws that form the basis of quality management. These principles have been identified to facilitate the achievement of quality objectives and form the foundation for effective quality management.

Quality management ensures that an organization, product or service is consistent. It is focused not only on product and service quality, but also on the means to achieve it.



Quality Management Principles



Customer focus

understanding customers' current and future needs and expectations

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

The principle of customer focus is more proactive than the concept of customer responsiveness. The proactive side involves working with customers to find better ways to meet the customer needs, and this goes beyond the expressed needs and wants of the customer to uncover the underlying purpose driving the customer requirements.



Leadership is NOT a position or a title, it is Action and Example.

Without clear and strong leadership, any business will struggle. The business should have clear goals and objectives (specific direction), and ensure its employees are actively involved in achieving those targets. To do this, the business will need to create and maintain the internal environment in which people can become fully involved. Communication between levels and functions of the organization will be essential for involvement and coordination. Top management should model organizational values at all times.

Strategic Leadership

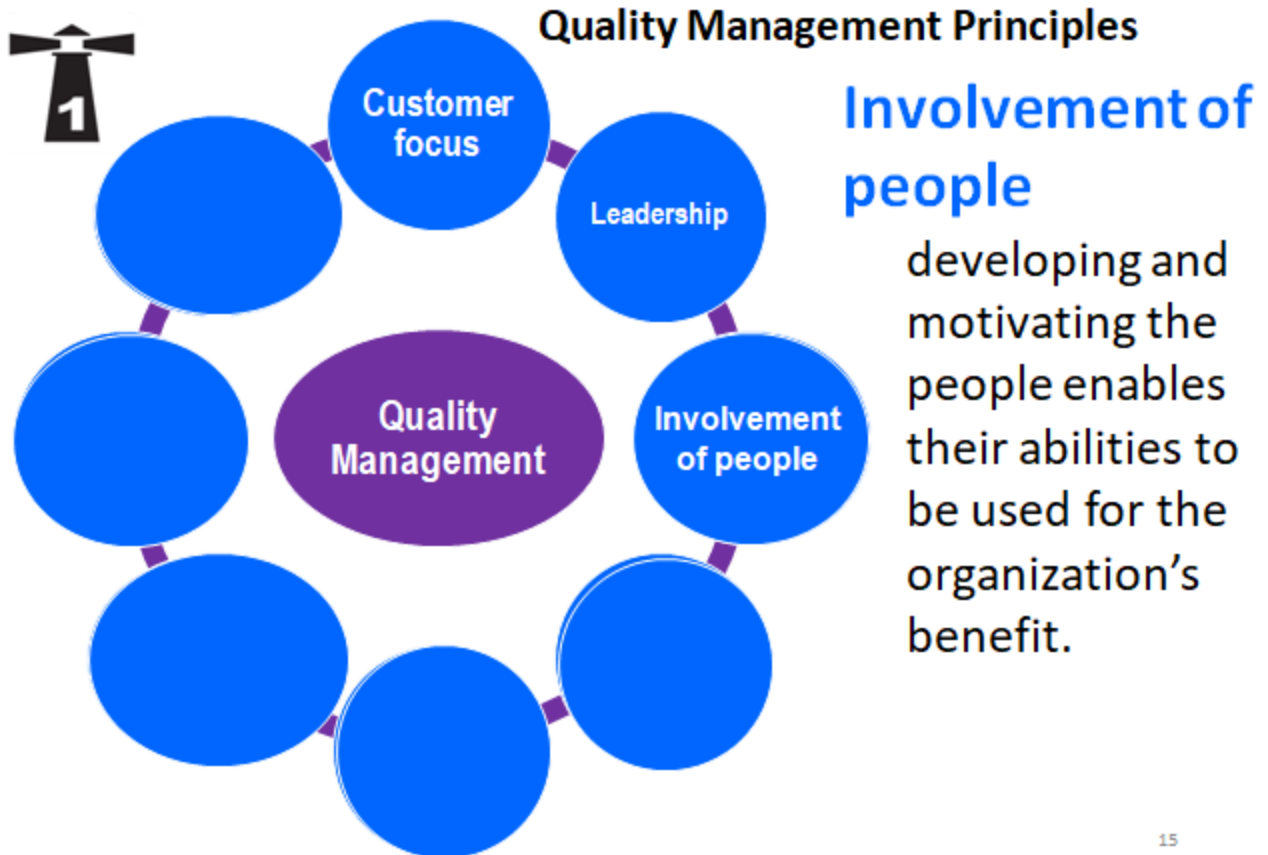
- Define the overall vision and mission of an organization
- Develop strategies, systems and structures to achieve the vision and mission
- Create both technical and social systems that are effectively integrated, and which address the needs of both customers and employees

Operational Leadership

- Ensuring that organizational processes are effectively carried out on a day-to-day basis.
- Monitoring performance
- Addressing constraints and hindrances
- Ensuring that employees understand what is to be done and are provided with the authority, knowledge and skills to do it

Top Management must be involved with

- Communicating to all employees on the importance of meeting customer and other requirements,
- Setting direction through a quality policy
- Defining expectations and monitoring results through the established quality objectives,
- Reviewing the organization's overall performance by conducting management reviews,
- Providing resources to achieve desired outcomes.



Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value and contribute to continual improvement. To do this, businesses must facilitate open discussion and sharing of knowledge and experience.

Common causes of variation (increase risk of defects) are often recognized by workers, but only laboratory management has the authority to change them to avoid repeated occurrence of the problem.

Intellectual waste - Not involving the workers in solving problems or making the process more efficient.



Quality Management Principles



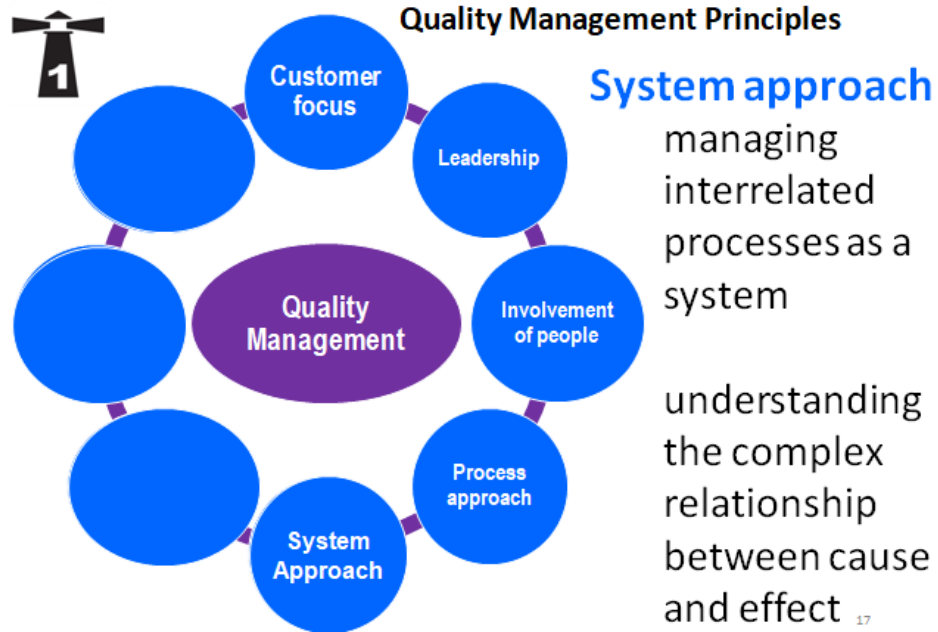
Process approach

ensuring
repeatability of
the process and
consistency in
quality which
conform to
specified
requirements

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All work can be viewed as a process which has inputs, steps, and output(s) and interfaces with other processes within an organization. Standardization of the inputs and steps of the process will produce products and services that consistently conform to specified requirements.

Therefore, a desired result is achieved more efficiently and effectively when activities and related resources are managed as a process.



This principle was not included in ISO 9001:2015 version but incorporated into the earlier principle, Process Approach to Quality Management.

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

The system approach recognizes that the products and services an organization provides to its customers are the result of processes linked together, from inputs to outputs – the chain of customers. All outputs have customers and all inputs have suppliers.

Within a large and complex laboratory system, there are sub-systems with their own objectives which are aligned to the overall objective of the organization. Therefore, in order to manage an organization as a system, one has to understand and to be able to visualize how each function/process works as a part of the organization, how the performance of the function contribute to the organization, and how it interacts within the organization.

Also, by Identifying, understanding and managing interrelated processes as a system, the organization can more effectively and efficiently achieve its objectives.



Quality Management Principles

Continuous improvement

continually seeking better ways of doing things

striving for perfection

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Continual improvement of the organization's overall performance must be a permanent objective of the organization. Improvement is necessary for an organization to maintain current levels of performance, to react to changes in its internal and external conditions, and to create new opportunities. In a way, it is learning from experience.

Among the most widely used tools for the continuous improvement model is the PDSA cycle.

Continual improvement is critical to optimizing the effectiveness of a quality management system and sustaining quality.



Factual approach to decision making

providing greater objectivity and confidence with decisions when based on the analysis and evaluation of data and information ¹⁹

Decisions based on evidence are more likely to produce the desired results or effects. However, ensure that the data and information are sufficiently accurate, reliable, and secure. Evidence-based decisions allow organizations to better manage risks and can promote the ability to review, challenge, and change opinions and decisions.



Quality Management Principles



**Mutually
beneficial
supplier
relationships**

managing
relationships with
interested parties,
such as suppliers

creating strong
partnerships

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First determine and prioritize the relevant interested party relationships, such as suppliers, partners, customers, investors, employees, and society as a whole, and their relationship with the organization that need to be managed.

When dealing with suppliers, focus on the control of the purchased items and the reliability and capability of the supplier in relation to the requirements defined by the organization. Ensure that the supplier has the capability to supply and deliver to the specified requirements of the organization, then measure performance and provide performance feedback to them to enhance improvement initiatives.

Recognize that established relationships balance short-term gains with long-term considerations.