

EVOLUTION OF THE ISO 9000 FAMILY OF STANDARDS

[UNI EN series 9000 April 1988]

- ❖ Unification of sector-specific Quality Assurance standards to create a single basic reference at the world-wide level
- ❖ Quality Assurance based approach in accordance with the Quality System

Third party “Compliance Audit” tool.

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[UNI EN ISO series 9000 December 1994]

- ❖ Process approach
- ❖ Effectiveness
- ❖ Reference to the Customer and Continual Improvement
- ❖ Difference between Quality Assurance and Quality Management

The basic concepts are set out in the standard, but not yet incorporated into the models of the ISO 9001-2-3 and 9004-1 Quality System.

EVOLUTION OF THE ISO 9000 FAMILY OF STANDARDS

[UNI EN ISO series 9000 December 2000]

- ❖ Process approach to the Quality Management System
- ❖ Customer focus (Needs and Satisfaction of Internal / External customers)
- ❖ Continual improvement approach (measurement, analysis and improvement)
- ❖ Effectiveness of the Quality Management system against established objectives

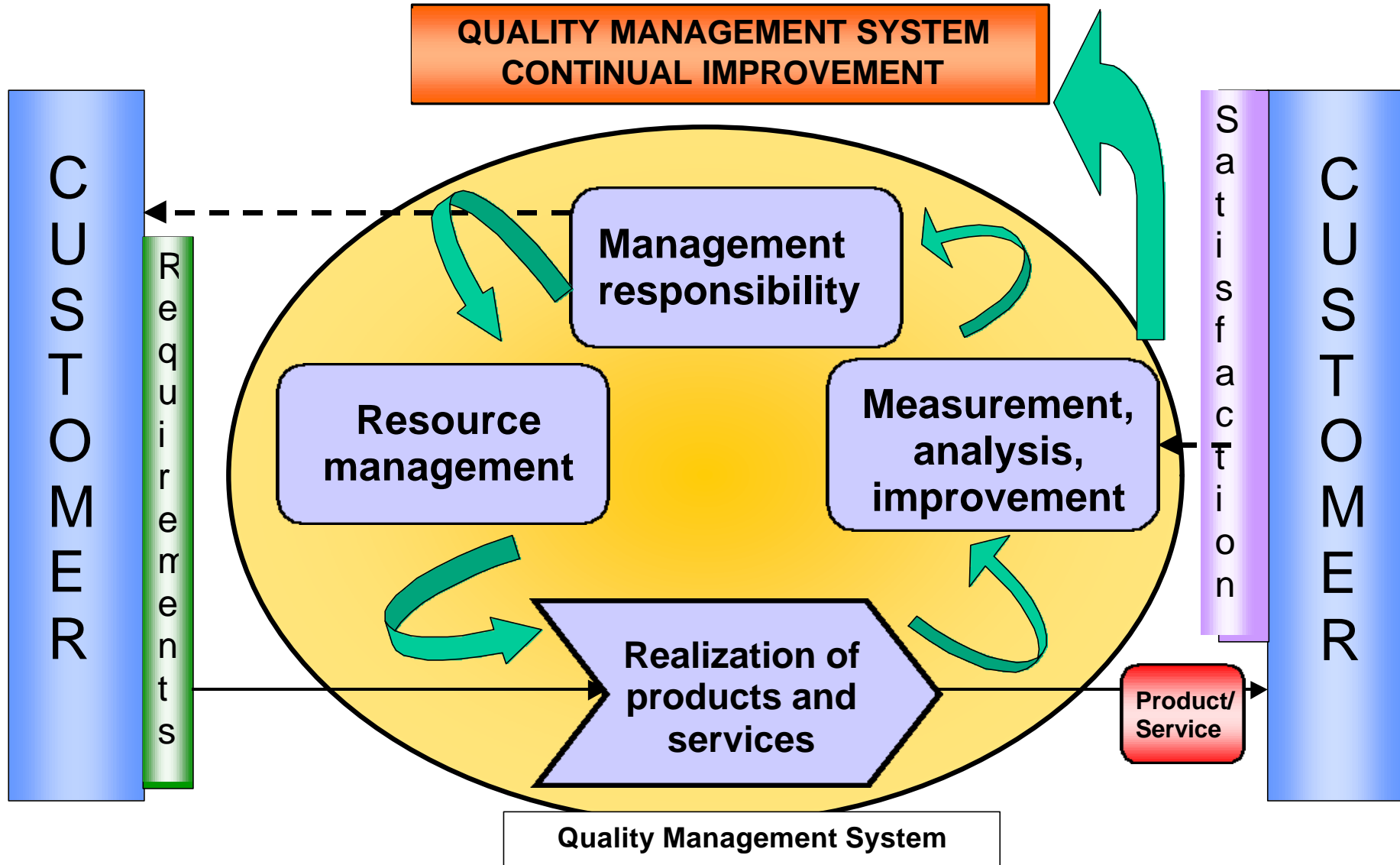
QUALITY MANAGEMENT SYSTEM (QMS)

(Quality Management System)

The QMS approach consists of:

1. Understanding the *needs and expectations of customers* and other interested parties;
2. Setting out the *quality policy and objectives* of the organisation;
3. *Determining the necessary processes* for the Quality Management System;
4. Establishing the *sequence and the interactions* between these processes;
5. Establish *criteria and methods* for ensuring the effective operation and the control of processes;
6. Ensuring the *availability* of the *information necessary* for deploying and monitoring the processes;
7. *Measuring, monitoring, analysing* the processes and taking the necessary actions for achieving the prefixed results and for continual improvement.

THE PROCESS MODEL



8 QUALITY MANAGEMENT PRINCIPLES

1. Customer focus

Organisations depend on their customers and therefore should:

- ❖ understand current and future customer needs
- ❖ meet customer requirements
- ❖ strive to exceed customer expectations

2. Leadership

Leaders establish the unity of purpose, direction and internal environment of the organisation.

They should create an internal environment in which people can become fully involved in achieving the organisation's objectives.

3. Involvement of people

People at all levels are the essence of an organisation and their full involvement enables their abilities and know-how to be used for the organisation's benefit.

continued 8 QUALITY MANAGEMENT PRINCIPLES

4. Process approach

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

5. 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.

6. Continual improvement

This should be a permanent objective of the organisation

continued 8 QUALITY MANAGEMENT PRINCIPLES

7. Factual approach to decision making

Effective decisions are based on the logical and intuitive analysis of data and information.

8. Mutually beneficial supplier relationships

Essential because it enhances the ability of both to create value.

CUSTOMER SATISFACTION

It is necessary to create methods / tools:

- ❖ for identifying the needs of the customer / market.
- ❖ for collecting and reviewing feedback about the quality perceived by the customers.

managing complaints is not sufficient, as this only detects customer dissatisfaction

CONTINUAL IMPROVEMENT

For the organisation, this entails:

- ❖ Commitment and full involvement of the managers.
- ❖ Active commitment at all levels (involvement of employees, teamwork, etc.)
- ❖ Development of innovation and creativity.
- ❖ Investing in people through training and qualifications.
- ❖ Capitalizing on experiences and success.

continued **CONTINUAL IMPROVEMENT**

For the organisation, this entails:

- ❖ Planning of future objectives and improvement processes (management review)
- ❖ Methods for tracking the objectives and the improvement processes.
- ❖ Record-keeping/documenting the product/process and the results obtained, and comparison with the desired results and the data for the competition.

CASE STUDY

Advantages derived from the implementation of a Quality Management System by Felletti-Spadazzi S.p.A.:

1. Involvement of all the company functions
2. Improved communication
3. More effective collaboration with problem-solving approach
4. Improved internal relationships
5. More efficient organisation as a consequence of managerial effectiveness

CASE STUDY: IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM IN A PHARMACEUTICAL DISTRIBUTION COMPANY OPERATING IN TRIVENETO REGION.(by Veronica Dettin)

continued CASE STUDY

Advantages derived from the implementation of the Quality Management System by Felletti-Spadazzi S.p.A.:

6. Involvement of all the company functions;
7. Reduction in nonconforming products
8. Enhanced image, customer satisfaction, improved competitiveness
9. Involvement of all employees in shared objectives

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CONCLUSIONS

To achieve the results described above the following were essential:

1. Strong, visible and ongoing commitment of the company's leadership
2. Continual supervision and commitment of management to evaluating the progress of the activities undertaken
3. Strong commitment on the part of the project managers.

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