
Appendix J

ISO/TC 176/SC 2/N 544R*

ISO 9000 Introduction and Support Package: Guidance on the Process Approach to Quality Management Systems

In conjunction with the publication of the International Standards ISO 9001:2000 and ISO 9004:2000, ISO/TC 176/SC 2 has published a number of guidance modules:

- Guidance on ISO 9001:2000 clause 1.2, “Application”
- Guidance on the Documentation requirements of ISO 9001:2000
- Guidance on the Process Approach to quality management systems
- Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000¹

Together these are being made available as the ISO/TC 176/SC 2 “ISO 9000 Introduction and Support Package.”

Feedback from users of the standards will be used to determine whether additional modules should be developed, or if these published modules should be revised.

The modules, and further information on the year 2000 ISO 9000 standards, may be downloaded from Web site: <http://www.bsi.org.uk/iso-tc176-sc2> .

1 INTRODUCTION

This guidance document is intended to help users of the ISO 9000:2000 series of standards to understand the concepts and intent of the “process approach” to quality management systems. It is not limited to the requirements of ISO 9001:2000, and is not intended to provide guidance for conformity assessment

*Secretariat of ISO/TC 176/SC 2, 17 May 2001

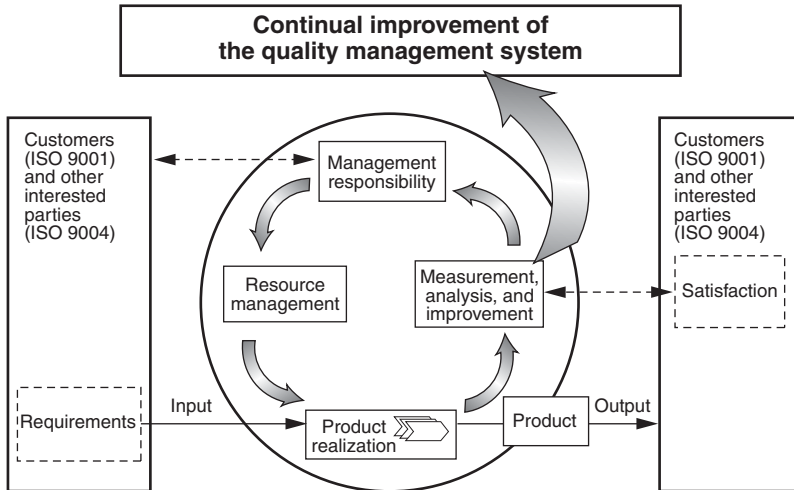


Figure J1 Model of a process-based quality management system (Taken from ISO 9000:2000).

purposes. It should not be interpreted as a source of additional requirements to those contained in ISO 9001:2000.

The new ISO 9000:2000 standards promote the adoption of a process approach when developing, implementing and improving a quality management system (QMS). The process approach is reflected in the structure of ISO 9004:2000 *Quality management systems—Guidelines for performance improvement*, and also in ISO 9001:2000 *Quality management systems—Requirements*. The “20 element” structure of ISO 9001:1994 has been replaced by this process-based quality management system, which is shown schematically in Figure J1.

This guidance document seeks to explain, in simple language, what is meant by a process, how processes can interact within a system, and how the Plan–Do–Check–Act (PDCA) cycle can be used to manage those processes. Examples of quality management system processes are given, as well as guidance on the implementation of the process approach in relation to ISO 9001:2000 requirements.

2 UNDERSTANDING THE PROCESS APPROACH

One of the eight quality management principles on which the ISO 9000:2000 series of standards is based relates to the “Process Approach” as follows:

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

ISO 9000:2000 clause 3.4.1 defines a “Process” as:

Set of interrelated or interacting activities which transforms inputs into outputs

Note 1 Inputs to a process are generally outputs of other processes.

Note 2 Processes in an organization (3.3.1) are generally planned and carried out under controlled conditions to add value.

Inputs and outputs are generally products that may be tangible and/or intangible. Examples of inputs and outputs may include equipment, materials, components,

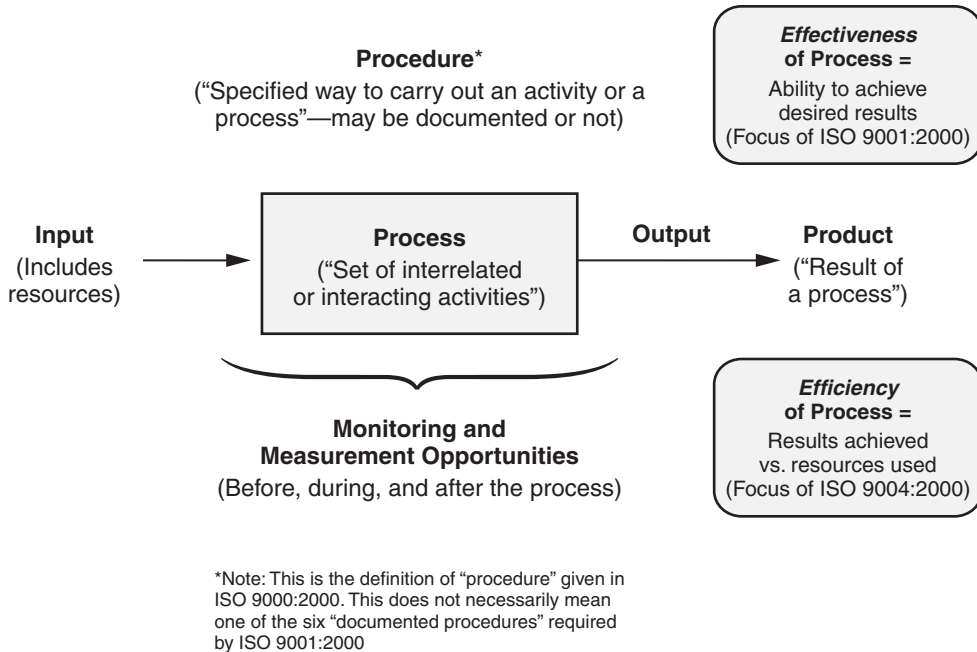


Figure J2 Schematic representation of a process.

energy, information and financial resources, among others. To perform activities within the process appropriate resources have to be allocated. A measurement system can be used to gather information and data to analyse process performance and/or input and output characteristics.

ISO 9001:2000 stresses the importance for an organization to identify, implement, manage and continually improve the effectiveness of the processes that are necessary for the quality management system, and to manage the interactions of these processes in order to achieve the organization's objectives. ISO 9004:2000 guides the organization beyond the requirements of ISO 9001:2000 by focussing on performance improvements. ISO 9004:2000 recommends an evaluation of the efficiency, as well as the effectiveness of the processes.

Process effectiveness and efficiency can be assessed through internal or external review processes and be evaluated on a maturity scale. These scales typically range in degrees of maturity from "no formal system" to "best-in-class performance." An advantage to this approach is that results can be documented and monitored over time to reach improvement goals. Numerous maturity tables have been developed for different applications. One such model is contained in ISO 9004:2000 annex A, "Guidelines for self-assessment."

3 THE PDCA CYCLE AND THE PROCESS APPROACH

The "Plan-Do-Check-Act" cycle was first developed in the 1920s by Walter Shewhart, and was popularised later by W. Edwards Deming. For that reason it is often referred to as "The Deming Cycle." Extensive literature exists about the

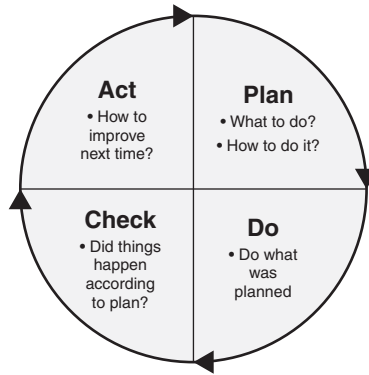


Figure J3 The “plan–do–check–act” cycle.

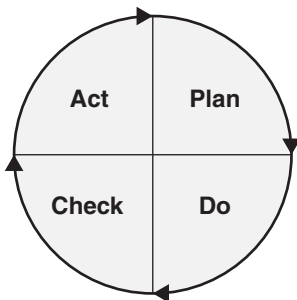
PDCA cycle in numerous languages, and users of the ISO 9000:2000 family of standards are encouraged to consult this for a deeper understanding of the concept.

The PDCA concept is something that is present in all areas of our professional and personal lives, and is used continually, either formally or informally, consciously or sub-consciously in everything we do. Every activity, no matter how simple or how complex, falls into this never-ending pattern.

Within the context of a quality management system, the PDCA is a dynamic cycle that can be deployed within each of the organization’s processes, and to the system of processes as a whole. It is intimately associated with the planning, implementation, control and continual improvement of both product realization and other quality management system processes.

Maintaining and continually improving the process capability can be achieved by applying the PDCA concept at all levels within the organization. This applies equally to high-level strategic processes, such as quality management system planning, or management review, and to simple operational activities carried out as a part of product realization processes.

The Note in Clause 0.2 of ISO 9001:2000 explains that the PDCA cycle applies to processes as follows:



Plan:

Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies

Do:

Implement the processes

Check:

Monitor and measure processes and product against policies, objectives, and requirements for the product and report the results

Act:

Take actions to continually improve process performance

4 UNDERSTANDING THE SYSTEM APPROACH TO MANAGEMENT

A second important quality management principle that is intimately linked with the Process Approach is the *system approach to management*, which states that “Identifying, understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its objectives.” Within this context, the quality management system comprises a number of inter-related processes. The processes needed for the quality management system include not only the product realization processes (those that directly contribute to making the product or delivering the service), but also numerous management, monitoring and measurement processes, such as resource management, communication, internal auditing, management review, and other processes. This can be seen schematically in Figure J3, which provides greater detail of the kind of processes that typically comprise the quality management system, divided among clauses 4–8 of ISO 9001:2000 and ISO 9004:2000.

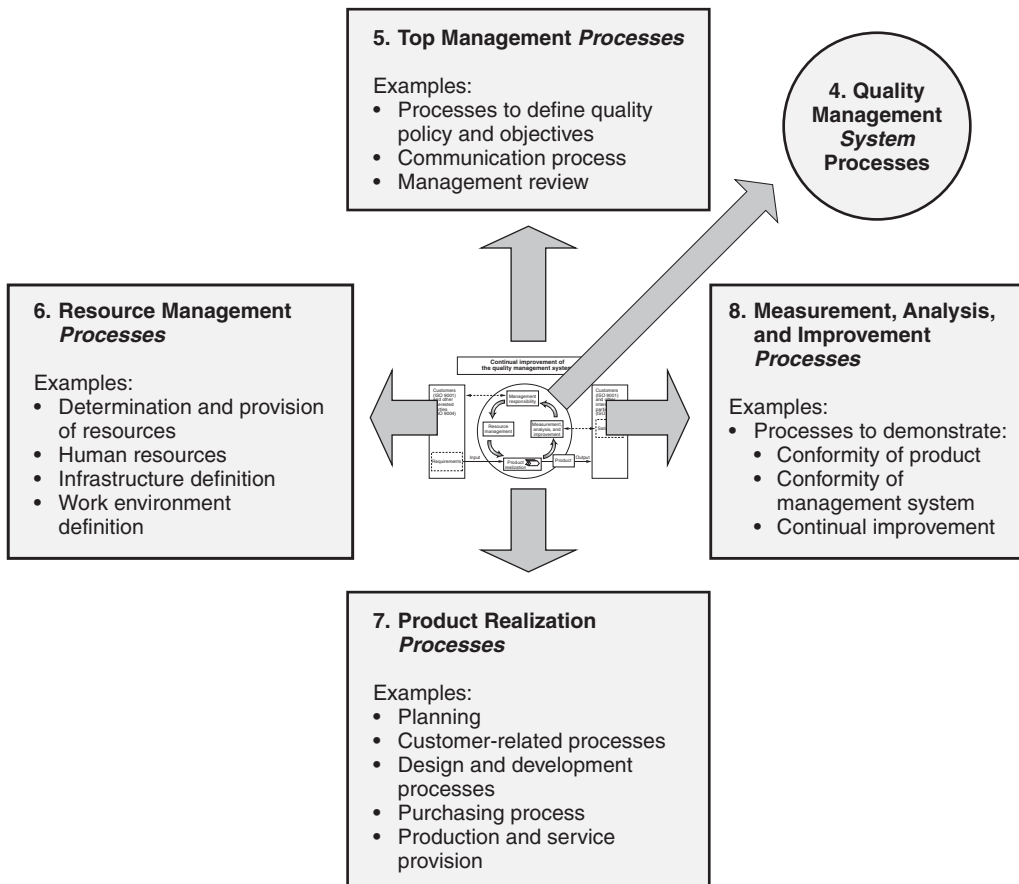


Figure J4 Schematic representation of typical quality management system processes, related to Figure J1.

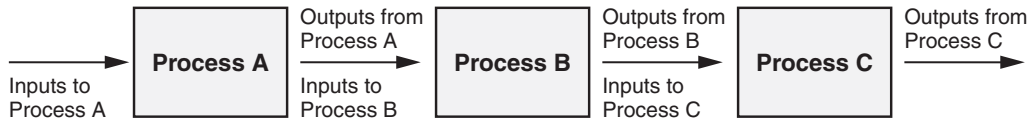


Figure J5 Chain of interrelated processes.

Individual processes rarely occur in isolation. Outputs from one process typically form part of the inputs into subsequent processes, as shown in Figure J4.

The interactions between an organization’s processes can often be complex, resulting in a network of interdependent processes. Inputs and outputs of these processes can often be related to both external and internal customers. An example of a network with interacting processes is shown in Figure J6. The model of the network of processes illustrates that customers play a significant role in defining requirements as inputs. Customer’s feedback on satisfaction or dissatisfaction of process output is an essential input to the continual improvement process of the QMS.

Note that the PDCA cycle can be applied to each individual process, as well as to the network of processes as a whole. Some important quality management system processes may have no direct interaction with the external customer. Process “F” in Figure J6, for example, may be an internal audit, a management review, maintenance, or a training process.

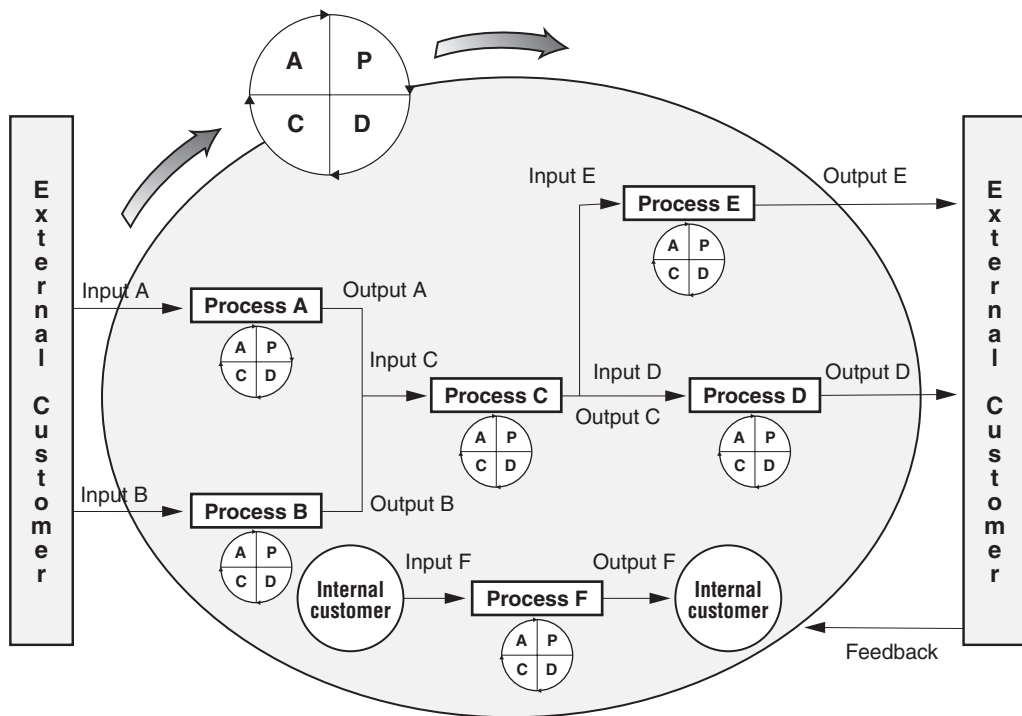


Figure J6 Typical network of interacting processes.

5 IMPLEMENTATION OF THE PROCESS APPROACH IN RELATION TO ISO 9001:2000 REQUIREMENTS

Clause 0.2 in the introduction of ISO 9001:2000 states, referring to the process approach:

When used within a quality management system process, such an approach emphasizes the importance of:

- a. the understanding and meeting of requirements,*
- b. the need to consider processes in terms of added value,*
- c. obtaining results of process performance and effectiveness, and*
- d. continual improvement of processes based on objective measurement.*

Further guidance is provided in clause 2.3 of ISO 9000:2000.

Within the context of ISO 9001:2000, the process approach includes the processes needed for product realization, and the other processes needed for the effective implementation of the quality management system, such as the internal audit *process*, the management review *process*, the data analysis *process*, and the resource management *process*, among others. All processes can be managed by using the “PDCA” concept.

Requirements for these processes are stated in the following clauses of ISO 9001:2000:

- 4 Quality management system
- 5 Management responsibility
- 6 Resource management
- 7 Product realization
- 8 Measurement, analysis and improvement

The general requirements for a quality management system are defined in clause 4.1 of ISO 9001:2000. Some guidance is given below on what questions an organization may choose to ask itself in order to address these requirements. It is stressed that these questions are only examples, and should *not* be interpreted as the only way to meet the requirements:

- a. Identify the processes needed for the quality management system, and their application throughout the organization.
 - What are the processes needed for our quality management system?
 - Who are the customers of each process (internal and/or external customers)?
 - What are the requirements of these customers?
 - Who is the “owner” of the process?
 - Are any of these processes outsourced?
 - What are the inputs and outputs for each process?
- b. Determine the sequence and interaction of these processes.
 - What is the overall flow of our processes?
 - How can we describe this? (Process maps or flow charts?)
 - What are the interfaces between the processes?
 - What documentation do we need?

- c. Determine criteria and methods required to ensure that both the operation and control of these processes are effective.
 - What are the characteristics of intended and unintended results of the process?
 - What are the criteria for monitoring, measurement and analysis?
 - How can we incorporate this into the planning of our QMS and product realization processes?
 - What are the economic issues (cost, time, waste, etc.)?
 - What methods are appropriate for data gathering?
- d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
 - What are the resources needed for each process?
 - What are the communication channels?
 - How can we provide external and internal information about the process?
 - How do we obtain feedback?
 - What data do we need to collect?
 - What records do we need to keep?
- e. Measure, monitor and analyse these processes.
 - How can we monitor process performance (Process capability, customer satisfaction)?
 - What measurements are necessary?
 - How can we best analyse gathered information (Statistical techniques)?
 - What does the result of this analysis tell us?
- f. Implement action necessary to achieve planned results and continual improvement of these processes.
 - How can we improve the process?
 - What corrective and/or preventive actions are necessary?
 - Have these corrective/preventive actions been implemented?
 - Are they effective?

6 DOCUMENTATION OF PROCESSES

Processes exist within the organization and the initial approach should be limited to identifying and managing them in the most appropriate way. ISO 9001:2000 requires that all processes “needed for the quality management system” be managed according to clause 4.1, “General requirements.” There is no “catalogue,” or list of processes that has to be documented. Each organization should determine which processes are to be documented on the basis of its customer and applicable regulatory or statutory requirements, the nature of its activities, and its overall corporate strategy.

In determining which processes should be documented the organization may wish to consider factors such as:

- Effect on quality
- Risk of customer dissatisfaction
- Statutory and/or regulatory requirements
- Economic risk
- Effectiveness and efficiency
- Competence of personnel
- Complexity of processes

Where it is found necessary to document processes, a number of different methods can be used, such as graphical representations, written instructions, checklists, flow charts, visual media, or electronic methods.

Further guidance on the documentation requirements of ISO 9001:2000 is given in ISO/TC176/SC2/N525R.

ENDNOTE

1. This module was developed jointly with ISO/TC 176/SC1/WG2. ISO/TC 176/SC1 was responsible for the development of ISO 9000:2000, *Quality management systems—Fundamentals and vocabulary*.