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THE PROCESS APPROACH IN ISO 9001:2015

Purpose of this paper

The purpose of this paper is to explain the process approach in ISO 9001:2015. The process approach can be applied to any organization and any management system regardless of type, size or complexity.

What is the process approach?

All organizations use processes to achieve their objectives.

A process:

- set of interrelated or interacting activities that use inputs to deliver an intended result

NOTE: Inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge).

The process approach includes establishing the organization's processes to operate as an integrated and complete system.

- The management system integrates processes and measures to meet objectives
- Processes define interrelated activities and checks, to deliver intended outputs
- Detailed planning and controls can be defined and documented as needed, depending on the organization's context.

Risk-based thinking, PDCA and the process approach

These three concepts together form an integral part of the ISO 9001:2015 standard. Risks that may impact on objectives and results must be addressed by the management system. Risk-based thinking is used throughout the process approach to:

- Decide how risk (positive or negative) is addressed in establishing the processes to improve process outputs and prevent undesirable results
- Define the extent of process planning and controls needed (based on risk)
- improve the effectiveness of the quality management system
- maintain and manage a system that inherently addresses risk and meets objectives

PDCA is a tool that can be used to manage processes and systems. PDCA stands for:

- P** Plan: set the objectives of the system and processes to deliver results (“What to do” and “how to do it”)
- D** Do: implement and control what was planned
- C** Check: monitor and measure processes and results against policies, objectives and requirements and report results
- A** Act: take actions to improve the performance of processes

PDCA operates as a cycle of continual improvement, with risk-based thinking at each stage.

What are the possible benefits?

- A focus on the more important (“high-risk”) processes and their outputs
- improved understanding, definition and integration of interdependent processes
- systematic management of planning, implementation, checks and improvement of processes and the management system as a whole.
- better use of resources and increased accountability
- more consistent achievement of the policies and objectives, intended results and overall performance
- process approach can facilitate the implementation of any management system
- enhanced customer satisfaction by meeting customer requirements
- enhanced confidence in the organization.

The practical steps in using a process approach in ISO 9001:2015 are explained below in Appendix A.

Other useful documents

ISO 9001:2015 The Process Approach
(a power point presentation on www.iso.org/tc176/sc02/public)

Appendix A

The process approach in ISO 9001:2015

In accordance with the requirements of ISO 9001 the following sequence of actions provides examples of how an organization may choose to build and control the processes of its quality management system. Performance can be managed and improved by applying the Plan-Do-Check-Act (PDCA) cycle. This applies equally to the system as a whole, to individual processes and to operational activities.

Steps in the process approach	What to do?	Guidance
PLAN		
Define the context of the organization	The organization should identify its responsibilities, the relevant interested parties and their relevant requirements, needs and expectations to define the organization's intended purpose.	Gather, analyze and determine external and internal responsibilities of the organization to satisfy the relevant requirements, needs and expectations of the relevant interested parties. Monitor or communicate frequently with these interested parties to ensure continual understanding of their requirements, needs and expectations.
Define the scope, objectives and policies of the organization	Based on the analysis of the requirements, needs and expectations establish the scope, objectives and policies that are relevant for the organization's quality management system.	The organization shall determine the scope, boundaries and applicability of its management system taking into consideration the internal and external context and interested party requirements. Decide which markets the organization should address. Top management should then establish objectives and policies for the desired outcomes.
Determine the processes in the organization	Determine the processes needed to meet the objectives and policies and to produce the intended outputs.	Management shall determine the processes needed for achieving the intended outputs. These processes include management, resources, operations, measurement, analysis and improvement.

<p>Determine the sequence of the processes</p>	<p>Determine how the processes flow in sequence and interaction.</p>	<p>Define and describe the network of processes and their interaction. Consider the following:</p> <ul style="list-style-type: none"> • The inputs and outputs of each process (which may be internal or external). • Process interaction and interfaces on which processes depend or enable. • Optimum effectiveness and efficiency of the sequence. • Risks to the effectiveness of process interaction. <p>Note: As an example, realization processes (such as those needed to provide the products or services delivered to a customer) will interact with other processes (such as the management, measurement, procurement in the provision of resources).</p> <p>Process sequences and their interactions may be developed using tools such as modeling, diagrams, matrices and flowcharts.</p>
<p>Define people or remits who take process ownership and accountability</p>	<p>Assign responsibility and authority for each process.</p>	<p>Top Management should organize and define ownership, accountability, individual roles, responsibilities, working groups, remits, authority and ensure the competence needed for the effective definition, implementation, maintenance and improvement of each process and its interactions. Such individuals or remits are usually referred to as the Process Owners.</p> <p>To manage process interactions it may be useful to also establish a management system team that has a system overview across all the processes and may include representatives from the interacting processes and functions.</p>

<p>Define the need for documented information</p>	<p>Determine those processes that need to be formally defined and how they are to be documented.</p>	<p>Processes exist within the organization. They may be formal or informal. There is no catalogue or list of processes that have to be formally defined. The organization should determine which processes need to be documented on the basis of risk-based thinking, including, for example:</p> <ul style="list-style-type: none"> • The size of the organization and its type of activities. • The complexity of its processes and their interactions. • The criticality of the processes. • The need for formally accountability of performance. <p>Processes can be formally documented using a number of methods such as graphical representations, user stories, written instructions, checklists, flow charts, visual media or electronic methods including graphics and systemization. However, the method or the technology chosen are not the goals. They can be used to describe processes, which are the means to achieve the goals. Effective and organized processes can then deliver consistent and accountable operations and the desired objectives and results which can then be improved.</p> <p>Note: For more guidance see the ISO 9000 Introduction and Support Package module <i>Guidance on the Documented Information Requirements of ISO 9001:2015</i></p>
<p>Define the interfaces, risks and activities within the process</p>	<p>Determine the activities needed to achieve the intended outputs of the process and risks of unintended outputs.</p>	<p>Define the required outputs and inputs of the process. Determine the risks to conformity of products, services and customer satisfaction if unintended outputs are delivered. Determine the activities, measures and inherent controls required to transform the inputs into the desired outputs. Determine and define the sequence and interaction of the activities within the process. Determine how each activity will be performed. Ensure that the management system as a whole takes account of all material risks to the organization and users.</p> <p>Note: In some cases the customer may specify requirements not only for the outputs but also for the realization of a process.</p>
<p>Define the monitoring and measurement requirements</p>	<p>Determine where and how monitoring and measuring should be applied. This should be both for control and improvement of the processes and the intended process outputs. Determine the need for recording results.</p>	<p>Identify the validation necessary to assure effectiveness and efficiency of the processes and system. Take into account such factors as:</p> <ul style="list-style-type: none"> • Monitoring and measuring criteria. • Reviews of performance • Interested parties' satisfaction. • Supplier performance. • On time delivery and lead times. • Failure rates and waste. • Process costs. • Incident frequency. • Other measures of conformity with requirements.

DO		
Implement	Implement actions necessary to achieve planned activities and results.	The organization should perform activities, monitoring, measures and controls of defined processes and procedures (which may be automated), outsourcing and other methods necessary to achieve planned results.
Define the resources needed	Determine the resources needed for the effective operation of each process.	Examples of resources include: <ul style="list-style-type: none"> • Human resources. • Infrastructure. • Environment. • Information. • Natural resources (including knowledge). • Materials. • Financial resources.

CHECK		
Verify the process against its planned objectives	Confirm that the process is effective and that the characteristics of the processes are consistent with the purpose of the organization.	The organization should compare outputs against objectives to verify that all the requirements are satisfied. Processes are needed to gather data. Examples include measurement, monitoring, reviews, audits and performance analysis.

ACT		
Improvement	Change the processes to ensure that they continue to deliver the intended outputs	<p>Act on the findings to ensure improvement of process effectiveness. (NOTE: Organizations may also wish to improve process efficiency, though it is not a requirement of ISO 9001 to do so).</p> <p>Corrective action as a result of process failure should include the identification and elimination of the root causes of the problems. 'System Thinking' recognizes that an event in one process may have a cause or effect in a dependent process. Causes and the effects may not be within the same process.</p> <p>Problem solving and improvement typically follows the essential steps of:</p> <ul style="list-style-type: none"> • define the problems or objectives • collect and analyze the data on the problem and relevant processes • select and implement the preferred solutions • evaluate the effectiveness of the solutions. • incorporate the solutions into the routine <p>Even when planned process outputs are being achieved and requirements fulfilled, the organization should still seek to improve process performance, customer satisfaction and reputation. This can be achieved, for example, by small-step continual improvement ("Kaizen"), breakthrough improvements and/or by innovation.</p>