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ISO 9001 Auditing Practices Group

Guidance on

Processes

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INTRODUCTION

“Process approach” is one of the quality management principles, which is given as: “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”.

Rationale for this quality management principle further explains that “the QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.”

An organization that is committed to ensuring the effectiveness and continual improvement of its QMS and enhancing customer satisfaction, should adopt the **“**process approach”. The process approach incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

Auditors should plan the audit based on the processes determined by the organization and prepare questions to assess the implementation of the process approach in the organization.

The auditor should consider the definition of process in ISO 9000: “set of interrelated or interacting activities that use inputs to deliver an intended result” and the description of the process approach in the Introduction to ISO 9001. This description is purely informative and does not introduce any additional requirement by itself but is useful to understand the way that the process approach is deployed in the standard. The following picture (figure 1 from the “Introduction”) facilitates understanding of a single process.

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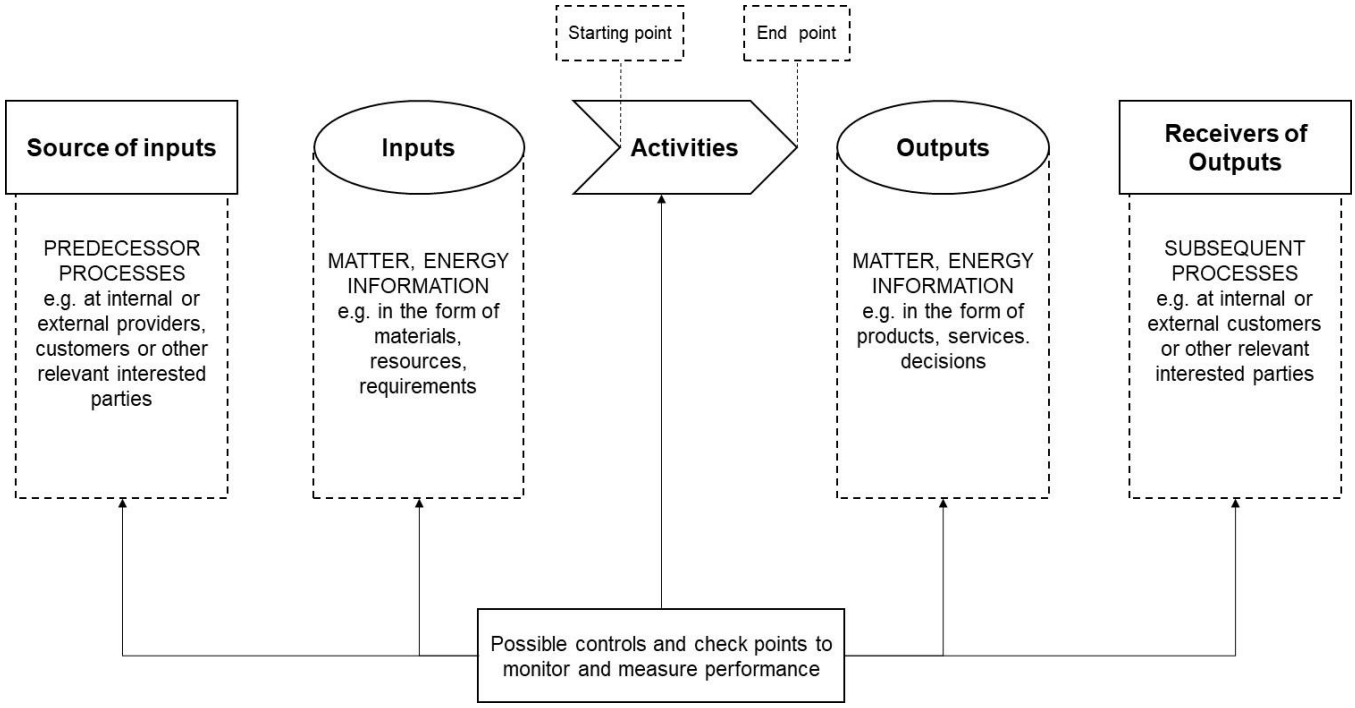

Figure 1

Clause 4.4 of ISO 9001:2015 sets up comprehensive requirements for an organization to determine and apply the processes needed for its quality management system, while also considering the PDCA cycle for continual improvement and integrating risk-based thinking. Accordingly, audits should be oriented towards analysing the processes of the organization.

The following diagram will assist auditors in establishing the sequence to audit the processes of the organization.

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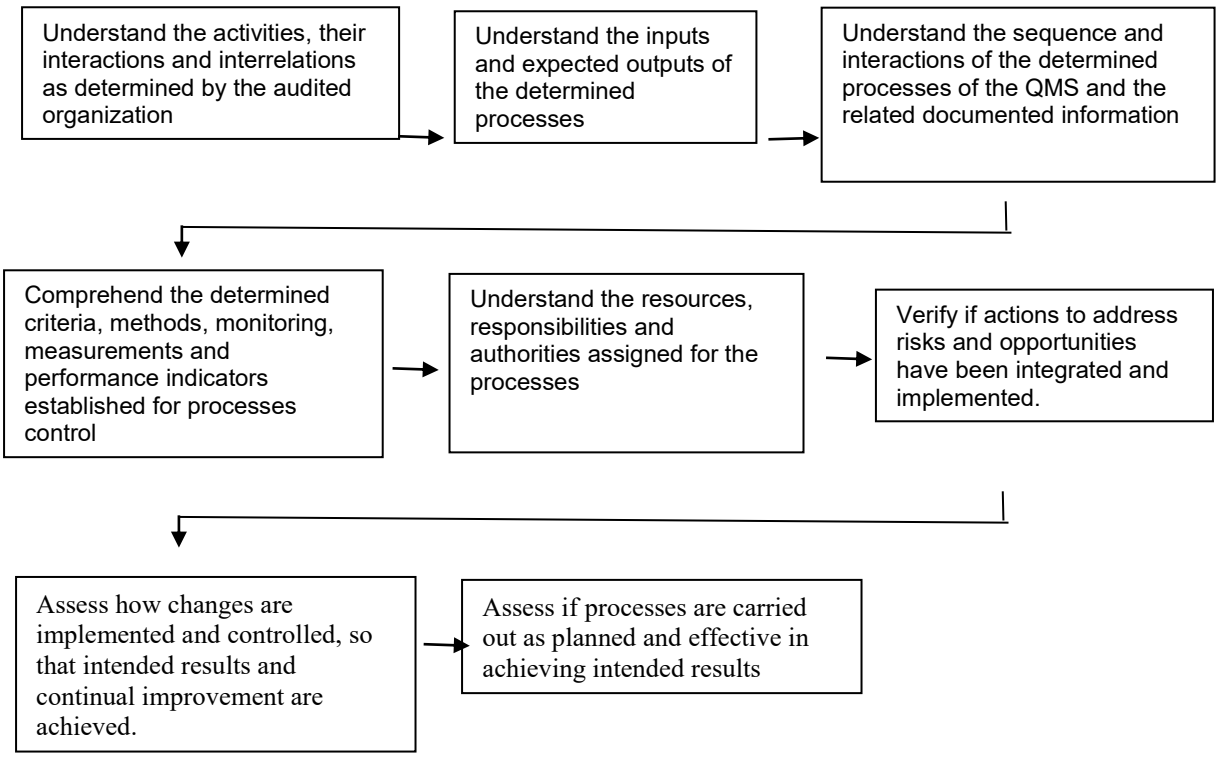

The level of documented information required for the processes (i.e. documents or records) should be determined by the organization, to the extent necessary to provide confidence that the QMS is effective. The standard does not specify format, media or content of the documented information.

If there is a specific customer, statutory or regulatory requirement for maintaining or retaining documented information, the auditor should verify conformity to those requirements.

Examples of possible documented information are process sheets, process maps, IT workflows, turtle diagrams. Documented information may also be integral to software programs and other digital media such as test software or ERP systems.

If the description of the process is not interpreted in the same way by the auditor and the auditee, the auditor should seek to understand the auditee's point of view and not impose his own view unless it is clear and supported with enough objective evidence that the requirements of the standard are not met. The same is true if the auditor believes that certain processes have not been correctly identified or are missing.

The auditor should assess if the organization has established adequate documented information to ensure that processes are understood to the extent necessary to support effective implementation of its processes.

The auditee has the right to use its own terminology. It is the responsibility of the auditor to ensure clear understanding of the auditee concepts to verify that the requirements of the standard are met.

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QUESTIONS RELATED TO THE PROCESS APPROACH

Below you will find some example questions for auditing the process approach. The code after the questions represent: P=plan, D=do, C=check and A=act.

- Can you explain to me what you do? D
- What information do you need to start your work? P
- How do you know how to do your job? P
- Where does the information come from? P
- What decisions are you responsible to make? D
- What is the result of your work? C
- Who receives the result of your work? D
- How do you know if you've done your job correctly? C
- What kind of verifications do you perform? C
- What records are kept? C
- Are there changes, how and why? A
- What can go wrong and what would you do? C/A

Auditors should evaluate the suitability for the intended purpose of the process performance indicators established for relevant processes. These may be used to monitor objectives.

PROCESSES SHOULD BE ANALYSED, MONITORED, MEASURED, AND IMPROVED

The auditor should be able to understand the criticality of the process being audited. This will facilitate the auditor's understanding of the linkage between the processes and the perceived risks.

The level of monitoring, measurement and improvement of each process will depend on the organization's context, its strategic intent and its determined risks and opportunities.

Auditors should be aware that the application of the process approach will be different from organization to organization, depending on the size and complexity of the organization and its activities. Special consideration should be given to the situation in small and medium enterprises (SME's), where there may be fewer processes.

Auditors should verify that established performance indicators are balanced, do not conflict with each other, are realistic, provide insights into process performance, and are understood throughout the organization.

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The auditor should evaluate if the organization's performance indicators allow for the effective operation and control of its processes, and if they relate to the risks and opportunities for those processes.

HELPING AN AUDITEE TO INTERPRET THE PROCESS APPROACH

During a stage 1 audit, an auditor may become aware that the auditee lacks understanding of the process approach. The auditor should refer the auditee to the ISO 9001:2015 standard requirements, introduction, and annexes. Additional references may be made for the auditee to access recognized information sources, such as the paper on "The Process Approach in ISO 9001:2015" (available from www.iso.org/tc176/sc02/public), which sets out different steps in the process approach and provides useful guidance with examples.

Auditees frequently identify unnecessary processes. Some are activities within processes. Others are defined as per clauses mirroring the standard regardless of their applicability. These do not fulfil the requirements of a process in the sense of ISO 9001:2015, nor do they accurately reflect the sequence and interrelation of activities within the QMS.

In this situation, an auditor should (at stage 1 audit) raise an issue regarding the need for a redefinition of the processes, based on e.g., the criticality of the activities and the process approach. This might be particularly relevant for SME's.

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Feedback from users is welcomed by APG/AAPG and will be used to determine the need for additional guidance documents, as well as for the revision of the current ones.

In case you wish to provide your feedback, the Group Secretary contact details are also available on these sites.

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