



International Organization for Standardization



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## ISO 9001 Auditing Practices Group

### Guidance on:

#### Processes

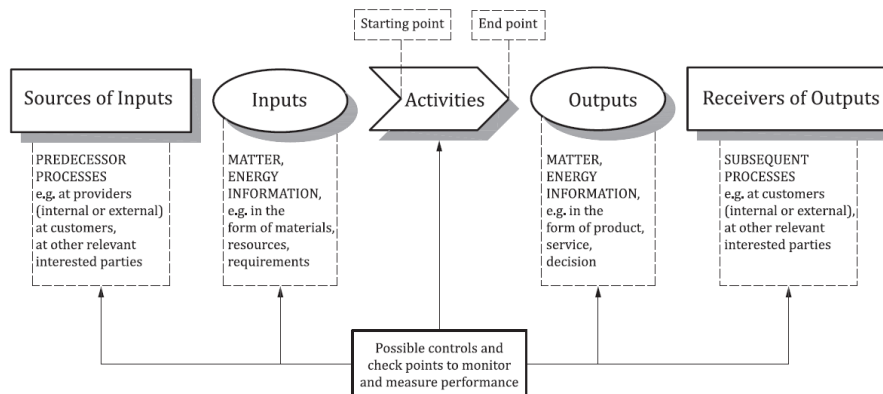
##### 1. Introduction

The use of the “process approach” is a mandatory requirement for ISO 9001:2015 and one of the most important for a quality management system. Auditors have to understand that auditing a QMS is auditing an organization’s processes and their interactions.

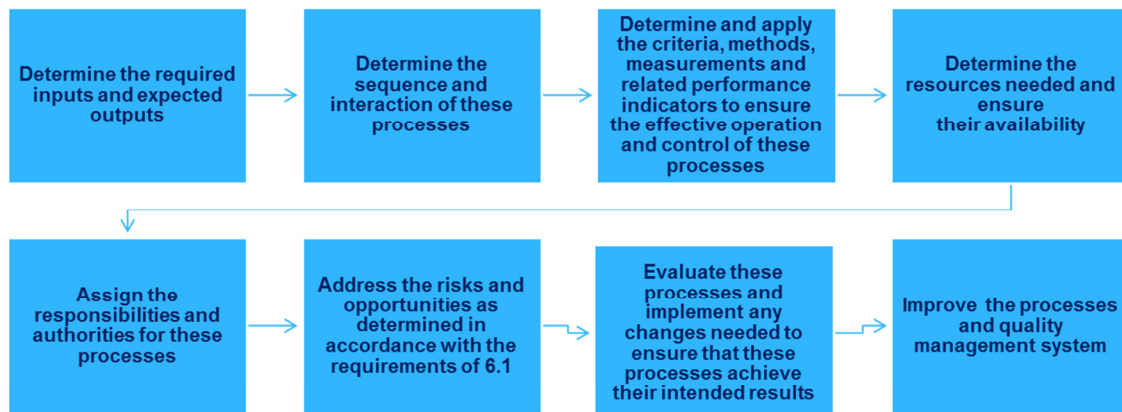
The “process approach” is one of the core quality management principles, which is given as: “Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system”.

The “rationale” to 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.”

The description of the process approach in the 'Introduction' to ISO 9001 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”) provides a good understanding of a single process.



Clause 4.4 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 analyzing the processes of the organization. The following diagram will assist auditors in establishing the sequence to audit the processes of the organization.



The level of documented information needed for the processes (i.e. documents or records) needs to be determined by the organization, to the extent necessary to provide confidence that the QMS is effective, although the standard does not define any specific format or content.

Examples of possible documents are: process sheets, process maps, IT workflows, turtle diagrams, etc.

If the description of a 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 auditee has the right to use its own terminology, provided the requirements of the standard are met. The auditor should mentally develop a cross-reference list to ensure consistency and better understanding.

During the audit, the auditor should determine whether there is a problem of different use of terminology only, or whether there is a lack of real implementation of the process approach by the auditee.

## **2. Objectives, inputs, outputs, activities and resources**

If the auditee does not understand that a process must have defined objectives (but they need not necessarily be quantitatively measurable), inputs, outputs, activities, and

resources, the auditor should try reformulating the questions to the auditee avoiding the use of QM jargon.

Below you will find some example questions for auditing the process approach. For more guidance see the annex to this paper, which outlines typical checklist items which may be used to audit any process within any organization.

- Can you explain to me your operations here?
- What are the basic jobs carried out in your department?
- What information do you need to start your work?
- Where does it come from?
- Who receives the result of your work?
- How do you know if you've done your job correctly?
- etc..

This should help the auditor to establish whether the processes are already defined, have clear inputs, outputs, objectives and so on. The auditor also need to verify that the organization has defined quality objectives for relevant processes that are aligned with its business objectives, and that these two sets of objectives do not conflict with each other.

The process performance indicators established for relevant processes may be used to monitor these objectives. In that case auditors should evaluate their suitability for the intended purpose.

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.

Auditors should verify that established performance indicators are balanced, do not conflict between each other, are realistic and understood throughout the organization.

### **3. Processes should be analysed, monitored, measured, and improved**

If there is an absence of any documented information, or other proof, to demonstrate that the organization's processes are analyzed, monitored, measured, and improved, this could result in the auditor issuing a nonconformity.

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.

The auditor should not lose sight of the overall direction of the audit, and get side-tracked by superfluous details. It is important that the auditor keeps a close eye on the information provided by the auditee and especially on any documented information where the auditee defines the interaction of its processes. Interviews should also be performed in such a way that the auditors can determine the inputs and outputs of the process being audited.

The auditor should be able to determine the importance of the process he is auditing at any time, and will therefore be able to keep sight of the overall direction of the audit. This will also help the auditor to understand the linkage between the processes.

During an audit, the auditor has an opportunity to check the auditee's description of the interrelation of its processes. The auditor should take some samples to see if the descriptions presented in the auditee's documented information are a proper reflection of the actual interrelation of the processes, as this will help determine if the process description is adequate.

Auditors must 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 auditors should not expect so many processes in their QMSs.

#### **4. Helping an auditee to interpret the process approach**

If an auditor is faced with a complete misunderstanding by an auditee, this situation should normally be identified at the 1<sup>st</sup> stage of initial certification audit.

The auditor should refer the auditee to recognized information sources, such as the paper on "*The Process Approach in ISO 9001:2015*" (available from [www.iso.org/tc176/sc02/public](http://www.iso.org/tc176/sc02/public)), which sets out different steps in the process approach and provides useful guidance with examples.

The auditee should also pay sufficient consideration to

- the establishment of process objectives,
- process planning,
- the availability of suitable documented information

Auditees frequently identify too many processes; some or all of them are activities, or defined as one per clause of the standard, which do not fulfil the requirements of a process, in the sense that ISO 9001 uses the concept. In this situation, an auditor should (in the 1<sup>st</sup> stage initial 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.

Also in this situation the auditor should refer the auditee to relevant ISO documents, such as The Process Approach in ISO 9001:2015 (see above) which gives clear guidance on this matter.

## **Annex A**

### **A generic list of questions for auditing**

By using this checklist an auditor can cover the majority of the requirements of ISO 9001

- 1) Who or what are the:
  - Processes
  - Process Owner
  - Personnel Interviewed
  - Documentation Reviewed
  - Records Sighted
- 2) What are the resources needed for the process?
- 3) Are these resources appropriate?
- 4) Are authorities and responsibilities for required resources defined, documented and known throughout the organization?
- 5) Are these persons competent?
- 6) Are competency criteria defined? What are these criteria?
- 7) How is competency evaluated, approved and monitored, and by which method(s)?
- 8) Are these methods effective? – refer to outputs
- 9) Are the resources adequate? Which are they?
- 10) Are records available and appropriately maintained?
- 11) What are the inputs to this process?
- 12) Are these inputs documented and reviewed by competent persons?
- 13) Is a description of the processes available and documented?
- 14) Are these descriptions controlled? – Verify the effectiveness of the organization's documented information control procedure.
- 15) Who are the "customers" (internal and external) of the processes?
- 16) What are the requirements of these customers?
- 17) What are the characteristics of the intended results of the process?
- 18) What are the characteristics of the unintended results of the process?
- 19) Are correction and corrective action applied as appropriate?
- 20) What are the criteria for monitoring, measurement and analysis?
- 21) How are these criteria incorporated into the planning of the processes?
- 22) Are the business performance issues taken into proper account?
- 23) What methods are used for data gathering?
- 24) What records are kept and how these are maintained?
- 25) What are the communication channels?
- 26) How is external and internal information about the process provided?
- 27) What are the outputs of the process? – Identify outputs.
- 28) Do these outputs provide evidence of effective implementation of the process?
- 29) How is process performance monitored?
- 30) Are appropriate controls defined?
- 31) What measurements are applied?
- 32) How is the gathered information analyzed?
- 33) How are the results of the analysis taken into account?

- 34) How is feedback obtained?
- 35) What data is collected?
- 36) Is the issue of improvement of the processes properly addressed? How? What are the results ?

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For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: [charles.corrie@bsigroup.com](mailto:charles.corrie@bsigroup.com).

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

[www.iaf.nu](http://www.iaf.nu)  
[www.iso.org/tc176/ISO9001AuditingPracticesGroup](http://www.iso.org/tc176/ISO9001AuditingPracticesGroup)

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