International Organization for Standardization   International Accreditation Forum

Date: 5 June 2009

ISO 9001 Auditing Practices Group
Guidance on:

Identification of processes

1. Distinguishing between the concepts of a process and an activity

If an auditee cannot distinguish between the concepts of a process and an activity, the auditor can briefly explain the differences by using the guidance (clause 2.4) and definition ((3.4.1) in ISO 9000 as background information. The auditor must be able to adapt to the auditee's situation. It is the auditor's responsibility to understand the auditee's systems and approach.

During the audit, the auditor should determine whether there is a problem of difference of terminology only, or whether there is a lack of real implementation of the process approach by the auditee. There may be a need to issue an NCR if the auditee is not fully implementing the requirements stated in ISO 9001, Clause 4.1. If this is simply a terminology problem, there should be no need to issue an NCR, if all the requirements of in Clause 4.1 are satisfied.

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.

2. A process has defined objective(s), input(s), output(s), activities, and resources

If the auditee does not understand that a process must have defined (but not necessarily measurable) objective(s), input(s), output(s), activities, and resources, the auditor should try reformulating the questions to the auditee avoiding the use of QM jargon, e.g. 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 (as per ISO 9001) are already defined, have clear inputs, outputs, objectives and so on.

3. Processes should be analysed, monitored and/or measured, and improved

If after applying the audit techniques outlined above, there is an absence of any records or other proof to demonstrate that the processes are analysed, and/or monitored, and/or measured, and/or improved, there would appear to be non-conformity with part of ISO 9001 Clause 4.1.

4. The auditee/auditor considers that each clause or sub-clause of ISO 9001 must be defined as a separate process

If the auditor considers this as the right approach, he should refer to relevant ISO documents, (notably the ISO/TC 176/SC 2 document N544 ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach) which clearly indicates the contrary.

If the auditee considers this as the right approach, it is recommended that the techniques outlined in section 2 (above) should be used.

5. Is the process approach as described in the 'Introduction' to ISO 9001 a requirement of the standard?

The description of the process approach in the 'Introduction' to ISO 9001 is purely informative and does not introduce a set of additional requirements by itself. Clause 4.1 specifies the steps necessary to implement a process approach with regard to quality management system processes, the Notes to clause 4.1 providing examples of processes needed for the quality management system. Audit methodologies must be oriented, accordingly, towards analyzing the processes of the organization.

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 .

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

www.iaf.nu
www.iso.org/tc176/ISO9001AuditingPracticesGroup

Disclaimer

This paper has not been subject to an endorsement process by the International Organization for Standardization (ISO), ISO Technical Committee 176, or the International Accreditation Forum (IAF).

The information contained within it is available for educational and communication purposes. The *ISO 9001 Auditing Practices Group* does not take responsibility for any errors, omissions or other liabilities that may arise from the provision or subsequent use of such information.