



International Organization for Standardization



International Accreditation Forum

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ISO 9001 Auditing Practices Group **Guidance on:**

Understanding the process approach

Helping an auditor to interpret the process approach

If an auditor does not understand or misunderstands the process approach, direct him or her to recognized information sources, such as the standard ISO 9000:2000 *Quality management systems – Fundamentals and Vocabulary* and the [ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach for management systems \(document ISO/TC176/SC2/N544\)](#), available from <http://www.iso.org/tc176/sc2>).

A certification body/registrar should ensure that all its auditors have received sufficient training regarding the new requirements in ISO 9001:2000, particularly those on the process approach. Thus, an auditor should realise that several steps are needed, including the following:

- determining the processes and responsibilities necessary to attain the quality objectives of the organisation;
- determining and providing the resources and information necessary;
- establishing and applying methods to monitor and/or measure and analyse each process;
- establishing and applying a process for continual improvement of the effectiveness of the QMS.

The process approach concept must be so well understood by auditors that they are not limited by the terminology in the standard; however, auditees may use their own “in-house” terminology. Auditors must be aware that the application of the process approach will be different from organisation to organisation, depending on the size and complexity of the organisation and its activities. Special consideration should be given to the situation in small and medium enterprises (SME’s), so that auditors should not expect so many processes in their QMSs.

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 1st stage audit.

The auditor should refer the auditee to recognized information sources, such as those indicated in the section above. (In particular, the referenced ISO/TC 176/SC 2/N544 document 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 records.

Auditees frequently identify too many processes; some or all of them are activities, which do not fulfil the requirements of a process, in the sense that ISO 9001:2000 uses the concept. In this situation, an auditor should (in the 1st stage audit) propose that the auditee performs a redefinition of its processes, based on e.g. the criticality of the activities. This might be particularly relevant for SME's.

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@bsi-global.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

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