

Auditing a quality management system (QMS) which has minimum documentation

There can be disagreement between an auditor and an auditee on the absence of certain documented procedures, when the auditee presents only a quality manual and the six documented procedures specifically required by ISO 9001.

The differences in view between the auditor and the auditee can arise from differences in the interpretation of the ISO 9001 requirements contained in clause 4.2.1, and the related note, which state:

'4.2.1 General: the quality management system documentation shall include documents needed by the organization to ensure the effective planning, operation and control of its processes. Note two: the extent of the quality management system documentation can differ from one organization to another due to

- the size of organization and type of activities
- the complexity of processes and their interactions
- the competence of personnel

The auditor should request information on the auditee's operating processes and subsequently ask questions, record answers and observe staff at all levels (including administrative personnel, process owners and operators), to confirm that the actual working status conforms to the descriptions given.

Thereafter, the necessity for any documentation should be evaluated in the light of the observed need for consistency, and the role that any documentation could play in avoiding any significant, identified risks.

The reader is referred to the advice given in document referenced ISO/TC 176/SC 2/N 525, ISO 9000 introduction and support package: guidance on the documentation requirements of ISO 9001.

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The ISO 9001 Auditing Practices Group is an informal group of QMS experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the IAF. It has developed a number of guidance papers and presentations that contain explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001.

JANUARY 2005

