

## The Need for a 2-Stage Approach to Auditing

Auditing ISO 9001:2000 requires auditors to obtain a good understanding of an auditee's quality management system (QMS) and the nature of its business. This is why it is beneficial for an organization to be visited prior to its certification audit and for a 1<sup>st</sup> stage audit to be conducted.

This 1<sup>st</sup> stage audit is primarily for scoping and planning a certification audit (the stage 2 audit) and to allow the auditor to obtain an understanding of the organisation. For example, to gain knowledge of its QMS, policies, objectives, risks, processes, locations, etc. It is also may be used for the auditing body to communicate its needs and expectations to the auditee.

Activities performed at a preliminary 1<sup>st</sup> stage audit include:

- Identification of the key risks of the business and related statutory, regulatory aspects and compliance
- An assessment of whether the auditee's defined processes are adequate to meet its objectives and customer requirements
- Conducting a Documentation Review
- This review should determine if the organisation's QMS documentation adequately covers all the requirements of ISO 9001:2000. The review would normally be carried out at the auditee's premises (unless otherwise requested and justified). As a result of this activity, a report should be provided that notes any deficient areas. As part of the documentation review, the auditor should assess the extent and availability of supporting procedures and process descriptions. Collecting necessary information regarding the scope of the organization's management system, processes and location(s)
- Drafting the future certification documentation, including the Scope statement
- Planning the certification (stage 2) audit, including the requirements for audit team selection
- Obtaining evidence that internal audits and management reviews are being planned, or performed, effectively
- Checking that the QMS is implemented and ready for the stage 2 audit, including appropriate level of documents and supporting records.
- If the system is lacking in any way, the auditor should note this in the audit report, so that the organisation has an opportunity to rectify deficiencies prior to its certification (2<sup>nd</sup> stage) audit.
- Agreeing a date for the stage 2 audit

This article is an edited version of 'The Need for a 2-Stage Approach to Auditing' from the website of the ISO 9001 Auditing Practices Group, and is reproduced courtesy of ISO and the IAF. These papers were developed on current best practice and therefore have not been formally endorsed as International Accreditation Forum (IAF) guidance or ISO TC176 interpretations. For further information about the Auditing Practices Group <http://isotc.iso.org/livelink/livelink/fetch/2000/2122/138402/138403/%203541460/customview.html?func=ll&objId=3541460&objAction=browse&sort=name>.

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.

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