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

Two stage initial certification audit

Auditing ISO 9001 requires auditors to obtain a good understanding of an auditee's quality management system (QMS), the nature of its business, as well as understanding its business strategy and its ecosystem. This is why it is beneficial to organize an initial visit to the organization by a representative of the audit team as part of the certification audit. This is called Stage 1 of the certification audit.

This 1st stage is primarily for scoping and planning the subsequent part of the certification audit (Stage 2) and to allow an auditor to obtain an understanding of the organization and to evaluate if that organization is ready for certification. For example, Stage 1 can be used to gain knowledge of the 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 1st stage include:

- ensuring that the client has prepared and is using any necessary management system documentation;
- evaluating the client's location and site-specific conditions, and undertaking discussions with the selected personnel in order to determine the preparedness of the client for the stage 2;
- reviewing the client's status and understanding regarding the requirements of the standard, in particular with respect to the identification of key performance indicators, processes, objectives and operation of the management system.
- collecting any necessary information regarding:
 - the scope of the management system,
 - the processes and location(s) of the client,
 - related statutory and regulatory aspects and compliance requirements (e.g. for quality, legal aspects of the client's operation, associated risks, etc.);
- reviewing the allocation of certification resources needed to effectively perform stage 2 of the certification audit and reaching agreement with the client on the related details, such as agreeing dates and scheduling, etc.;

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- providing a focus for planning the stage 2 of the audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;
- evaluating if internal audits and management reviews are being planned and performed, and whether the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.

There is no expectation that Stage 1 requires a formal audit plan or audit report. However, in order that Stage 1 can be efficient, the organization's representative should be informed in advance of the timing and objectives of the Stage 1 visit. Similarly if it appears during Stage 1 that the management system is lacking in any way, the auditor/ Certification body should inform the organization formally, so that the client has an opportunity to rectify the identified deficiencies prior to Stage 2 of the certification audit.

An audit in 2 stages does not normally need to be performed for each certification audit. However in the event of significant changes to the Quality Management system (e.g. important changes in the client's regulatory environment) then a complete or partial Stage 1 may be appropriate when planning the next certification audit.

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.

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