



International Organization for Standardization



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

AUDIT PLANNING

There are two levels of planning – the audit programme (identifying the audit activities during the certification cycle) and the audit plan (showing how a single audit is planned).

The important areas of the organisation and areas where there has been recent change or past non-conformity should be scheduled as a priority. Audits may need to be timed to suit the cycles of production or other activities, particularly if seasonal or sporadic. So, although one may have heard that all processes/areas need to be audited every year, it would be quite acceptable to take a risk-based approach and to audit some areas less frequently and instead focus on specific critical areas in a single year provided there is recorded justification.

How does one develop a programme?

If the certification client operates shifts, it would be wise to find out what happens on the evening and/or night shifts. Organizations may operate all shifts identically but, in others, the night shift may operate without appropriate supervision and/or technical support. Please, see clause 9.1.3.5 of ISO/IEC 17021-1.

The audit programme should ensure that the scope of each audit event is clear. An audit programme can be changed to suit changing circumstances (e.g. availability of auditee, availability of resources, holidays etc.) but should still achieve the overall intent of the programme.

For example, when auditing measuring equipment, consider combining the audit with the processes where measurement takes place and where the results of measurement are used; this way the sampling can be related to the results through the measurement process. The concept of the “internal customer” should be explored and customer satisfaction between internal functions should be considered (e.g. how well does the maintenance function ensure equipment up-time?).

How does one develop an audit plan?

Development of an audit plan should be done in collaboration with the certification client;

to discuss the time allocation, whether there are any particular issues that should be included in the audit and access to people, locations and documented information. As far as possible, it is advisable to obtain necessary information before planning of the audit commences.

USEFUL TIPS TO AUDITORS

- Develop a plan to give value to the organisation and satisfy requirements of Accreditation Bodies
- Plan to audit linked processes to explore synergies and “internal customer” issues
- Audit plans should be developed with the auditee if possible
- Available documented information should be reviewed before the audit to aid time allocation and understand sampling
- Checklists can improve the quality of audits but understand how they can and design them to promote the quality of audits (*Please, see ISO 9001 Auditing Practicing Group Guidance on: Checklist*).
- Use the outcome of Stage 1 audit to plan the stage 2 (*Please, see APG paper on Value of 2 stage audits*). It is strongly recommended to conduct Stage 1 audit at the client’s premises.
- Based on the outcome of Stage 1 or previous audits allocate more time to processes and/or areas with “higher risk”
- Develop the plan around the processes – not the clauses of the standard.
- Linked processes are best planned to be audited together and by the same auditor so that the linkages and interdependencies can be explored in the audit.
- Arrange an interview with Top Management straight after opening meeting for evaluation of context of the organization, strategic direction, understanding of relevant interested parties and leadership.
- Conduct the audit of “internal audit” last
- Consider whether aspects of a system where there is no standalone process can be audited as part of observation or interviews with auditees. If this approach is used, it is good policy to include, on the audit plan, a statement such as “*The conformity to all relevant requirements of ISO 9001 will be verified during the audit of related processes*”.

Examples of such areas where there may be no standalone process include:

- Awareness of Quality Policy
- The effectiveness and commitment of leadership
- Internal/external communication and awareness
- Fulfilment of objectives and link to the overall objectives (but it is recommended to ask top management about the way they set objectives)
- Process environment and infrastructure
- Competence of people (an understanding of the work people perform, can ensure the relevance of recorded experience, skills, training and knowledge; alternatively this can be audited with Human Resources if there is such a function).
- Documented information: (evidence of control, types of documents etc. This can then be used to provide input for the auditing the process of retaining and maintaining documented information).
- Improvement

Table 1: Extract of an example audit plan, considering this approach:

Time		Topic	Auditor	Auditee (to be completed by the client)
from	to			
<i>The conformity to all relevant requirements of ISO 9001 will be verified during the audit of related processes</i>				
Date: select				
9:00	9:30	Opening meeting		
9:30	11:30	Strategic direction and objectives; major changes in the last period; Context of the organization; Leadership		
11:30	13:00	Planning of objectives; processes, risk and opportunities, plan for monitoring, measurement and analysis.		
1300	1400	break		
1400	1600	Process 1 (e.g. Marketing and Sales)		
1600	1730	Process 2 (e.g. design and development)		
1730	1800	Daily wrap-up meeting		

Time		Topic	Auditor	Auditee
from	to			
Date: select				
9:00	9:15	Brief meeting: follow-up from audit issues from Day 1		
9:15	11:30	Process 3: e.g. manufacturing		
11:30	13:00	Process 4: e.g. packaging and logistics		
1300	1400	Break		
1400	1500	Human Resources: Competence, Training Planning		
1500	1600	External Provision of products and services		
1600	1700	Internal audits		
1700	1730	Auditor internal meeting		
1700	1800	Closing meeting		

Note: Ensure presence of Top Management for the Opening Meeting, the interview on: Strategic direction and objectives; Context of the organization; Leadership and the Closing Meeting.

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 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

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