International Organization for Standardization   International Accreditation Forum

ISO 9001 Auditing Practices Group
Guidance on:

Context

In order for an organization to have an effective quality management system (QMS), the QMS should be aligned with its strategic direction and take into account the internal and external issues that are relevant, when planning to achieve its objectives.

For the purpose of effective planning the organization needs to understand:
- its status,
- what it wants to achieve, and
- its strategy on how to achieve it.

(If you don't know clearly your starting point for your journey it will be difficult to achieve the desired destination.)

Auditors need to evaluate whether the organization has addressed these issues.

1.   Understanding the organisation and its context

There are many ways and supporting techniques for organizations to observe and analyse their context. The output from this activity should be evident in the determined risks and opportunities. Although there is no requirement for documented information in this section (ISO 9001:2015, clause 4.1), most organisations will find it useful to retain documented information to help understand the rationale and level of understanding of their challenges (e.g. "known knowns, known unknowns and unknown unknowns").

The information which might be helpful in this process could include:
- Business plan
- Review of strategy plans
- Competitor analysis
- Economic reports from business sectors
- SWOT analysis
- Minutes of Meetings
- Action lists
- Diagrams, Spreadsheets, Mind mapping diagrams
- External consultant's reports

The auditor should approach this area through an interview with members of the organization's top management. It should be evident whether top management have adequately considered their organization's context; the evidence of this may be adequately demonstrated by showing how the review outputs became the inputs into the QMS planning process (risk based thinking). However, in exploring the nature of the risks and

opportunities, the auditor should be able to understand the adequacy of the organization's review of its context.

2. Understanding the needs and expectations of interested parties

Auditors should understand and evaluate the way an organization decides on the requirements of interested parties which are relevant for the QMS by considering:
- the range of interested parties taken into account,
- criteria to select relevant interested parties,
- aspects to select relevant requirements.

Auditors should be able to conclude on the appropriateness of these practices and the way this information is reviewed and monitored, such as through management reviews.

Examples of relevant interested parties are given in ISO 9000:2015, definition 3.2.3, and clarification related to these requirements is provided in ISO 9001:2015, Annex A, clause A.3.

The relevant requirements of those relevant interested parties should be evident as inputs into the planning process, as potential risks and opportunities. Again, although there is no requirement to retain documented information, it would be expected that an organisation would keep some account of its analysis for ongoing and future reference. This could be expressed, for example, as:

- Minutes of meetings
- Tables
- Spreadsheets
- Databases
- Hyperlinks
- External documentation
- Quality manual (if organization decides to have one)
- Etc.

Auditors should conduct this review in an interview with top management and follow these issues throughout the audit. If documented information is not provided, auditors need to collect objective evidence that the outputs of this activity are consistently reflected in the review of risks and opportunities, external documentation, communication and other relevant areas of their QM.

3. Determining the scope of the quality management system

The scope of the QMS in many cases is self-evident and defined by the activities taking place at a single location. The scope of the QMS will become more challenging in circumstances where there is:

- outsourcing
- logistics
- multiple sites
- service centres
- servicing at customer premises
- collaborative products and services

From a review of the nature of the organisation's operations, products and services, the extent of the QMS should be clear. This should be expressed in the extent of processes and controls which the organisation has established.

See the ISO 9001 Auditing Practices Group paper on "Scope of ISO 9001, Scope of Quality Management System and Scope of Certification" for further information.

4. Quality Management system and its processes

The extent (scope) of the QMS should be evident in the documented information supporting the process approach. Such documentation could include:

- process diagrams (input – process – output)
- diagrams showing process linkages (inputs / outputs / customer)
- overlays showing the locations of activities
- identification of outsourced processes
- resource diagrams (e.g. capacity analysis, value stream mapping, "Lean"....)
- programmes

See the ISO 9001 Auditing Practices Group paper on "Processes" for further information.

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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