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ISO 9001 Auditing Practices Group

The *ISO 9001 Auditing Practices Group* is an informal group of quality management system (QMS) experts, auditors and practitioners drawn from the ISO Technical Committee 176 *Quality Management and Quality Assurance* (ISO/TC 176) and the International Accreditation Forum (IAF).

It has developed a number of guidance papers and presentations (see "QMS auditing topics" below) that contain ideas, examples and explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001:2000 *Quality management systems - Requirements*.

The guidance is primarily aimed at QMS auditors, consultants and quality practitioners, but is not definitive. The papers and presentations reflect a number of different views in QMS auditing. As such, their content may not always be consistent. It is not intended that the guidance will be used as specified requirements, an industry benchmark, or as criteria that all QMS auditors, consultants or practitioners have to follow.

QMS auditing topics

- The need for a 2-stage approach to auditing
- Measuring QMS effectiveness and improvements
- Identification of processes
- Understanding the process approach
- Determination of the “where appropriate” processes
- Auditing the “where appropriate” requirements
- Demonstrating conformity to the standard
- Linking an audit of a particular task, activity or process to the overall system
- Auditing continual improvement
- Auditing a QMS which has minimum documentation
- How to audit top management processes

- The role and value of the audit checklist
- Scope of ISO 9001:2000, Scope of Quality Management System and Defining Scope of Certification
- How to Add Value during the audit process
- Auditing competence and the effectiveness of actions taken
- Auditing Statutory and Regulatory requirements
- Auditing the Quality Policy and Quality Objectives
- Auditing ISO 9001, Clause 7.6 *Control of monitoring and measuring devices*
- Making effective use of ISO 19011
- Auditing Customer Feedback processes

A "Zip" file of all the above documents is also available.

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. Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsi-global.com.

The other papers and presentations may be downloaded from the web sites:

www.iaf.nu
www.bsi.org.uk/iso-tc176-sc2

Disclaimer

This paper has not been subject to an endorsement process by the International Organization for Standardization (ISO), ISO Technical Committee 176, or the International Accreditation Forum (IAF).

The information contained within it is available for educational and communication purposes. The *ISO 9001 Auditing Practices Group* does not take responsibility for any errors, omissions or other liabilities that may arise from the provision or subsequent use of such information.

Auditing the control of monitoring and measuring devices

The following information is provided as guidance for auditing the processes associated with control of monitoring and measuring devices, and on the potential exclusion of clause 7.6 from the scope of an organization's quality management system**.**

In auditing these processes, it is important for the auditor to understand the difference between:

- "*monitoring*" and "*measurement*", and
- "*equipment*" and "*device*s".

a) monitoring and measurement

- *monitoring* implies observing, supervising, keeping under review (using monitoring devices); it can involve measuring or testing at intervals, especially for the purpose of regulation or control
- *measurement* considers the determination of a physical quantity, magnitude or dimension (using measuring equipment).

b) devices and equipment

- *devices*: A device may deliver either qualitative (attribute based) or quantitative results. Examples of devices include
  - physical devices, e.g. a ship's flotation/load line, an overflow "tell-tale" pipe
  - non-physical devices, e.g. records of the rate of customer returns, survey questionnaires
  - equipment or "measuring equipment", see below;
- *equipment*: For the purposes of ISO 9001 equipment is regarded as a subset of devices. Equipment may be separated into two categories:
  - indicative equipment, for example an emergency flashing lamp, an electrical power on/off indicator, a "go/no-go" gauge, a fuel gauge "low-level" indicator
  - "measuring equipment", defined in ISO 9000, clause 3.10.4 as follows:

  "*measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process"*

Various parts of clause 7.6 address the topics of monitoring and measurement, devices and equipment. The first two paragraphs address all of these items. The third paragraph, including bullets a) to e), and the first two sentences of the fourth paragraph, are only directed at "measuring equipment". The last sentence of the fourth paragraph and the final paragraph once again address all of them. The standard is clear in this respect, but its correct interpretation requires the auditor to make a close analysis of its precise wording.

The standard only requires "measuring equipment" to be calibrated as "… *needed to provide evidence of conformity of product to determined requirements"* either by product or process measurements.

Auditing the control of monitoring and measuring devices

However, there are situations where “measuring equipment” may be used for indicative purposes only, and therefore may not need to be calibrated. An example is an ammeter being used to indicate current flow, not to measure the current.

Where it is not possible to calibrate monitoring and measuring devices they should be verified or validated. Examples include: a pilot study for a survey questionnaire, comparisons for sensory testing, etc.

From the description of monitoring and measurement, devices and equipment above it can be seen that it is unlikely that an organisation will be able to exclude the whole of clause 7.6 from the scope of its quality management system. If it explicitly does not use “measuring equipment” the organisation may be able to exclude the requirements of the third paragraph, bullets a) to e) and the first two sentences of the fourth paragraph.

Additional explanation and examples are given in the ISO Handbook: *ISO 9001:2000 for Small Businesses – What to do, Advice from ISO/TC 176.*