

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 to assist in the evaluation of justifications for the exclusion of clause 7.6 from the scope of an organization's quality management system.

This paper provides guidance only for the auditing of control of physical devices and is not to be used for assessing the validity of intangible outputs from qualitative attribute based processes such as education, training and customer satisfaction reviews. If examination papers, surveys, performance evaluation questionnaires etc are considered to be monitoring devices it is suggested that these should be controlled as a part of the validation of processes (see clause 7.5.2).

In the auditing of monitoring and measuring processes, it is important for auditors to understand the difference between monitoring and measuring:

- 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
- measuring considers the determination of a physical quantity, magnitude or dimension (using measuring equipment)

While measuring equipment is defined in ISO 9000 clause 3.10.4 as 'measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process', the standard only requires 'measuring equipment' to be calibrated when it is used for measuring purposes 'to provide evidence of conformity of product to determined requirements' either by product or process measurements.

Equipment and devices may be used for indication, monitoring or measuring. The same equipment could be used for all these three functions.

For example, in some industries, a pressure gauge may be used:

- as an indicator (e.g. to ensure that the pressure is present)
- as a monitoring device (e.g. to ensure that the pressure is stable and the process is under control); and
- as measuring equipment (e.g. where the accurate value of the pressure is important for the quality of product)

However, the level of control depends on the intended use and determines whether or not it should be calibrated or verified. The depth and degree of such confirmation may vary, depending on the nature of products, services and related risks.

In cases where the organization makes use of measuring equipment, evidence should be obtained that the metrological needs related to the production or service processes have been properly identified/specified and that the measuring systems have been designed and are operated and maintained in such a way as to fulfil the applicable metrological needs.

Auditors should confirm that, in addition to providing the necessary calibration records and assuring the related measurement uncertainty and traceability, the organization is aware of and has implemented, as appropriate, a metrological confirmation system as described in ISO 10012 adequate to the extent and types of the measurements performed.

From the description above, the organization should be able to decide whether or not all or part of the requirements of clause 7.6 may be excluded.

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

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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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