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ISO 9001 Auditing Practices Group Guidance on:

Auditing the control of monitoring and measuring equipment

The following information is provided as guidance for auditing the processes associated with control of monitoring and measuring equipment, 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**.**

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 equipment); 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.

Depending on the specific circumstances, measuring or monitoring equipment can be used either for indication, monitoring or measuring purposes. In some cases the same type of equipment could be used for all these three functions, for example, 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).

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However, the level of control depends on the intended use and determines whether or not it should be calibrated or validated. 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.

Some organizations such as Hotels, Restaurants, Education Centers, Consultants, Public Services, among others, perform monitoring and measuring activities utilizing as "monitoring or measuring equipment" surveys, examination papers, questionnaires, statistical reports, etc, due to the nature of their product.

These types of "equipment" should be controlled and validated accordingly to ensure that they provide consistent means of monitoring and measurement of the processes, product/service and customer satisfaction.

It is appropriate to address these types of "equipment" whilst auditing conformance with clause 8.2 "Monitoring and Measurement". If an organization can demonstrate appropriate controls of such "equipment" under this clause, an auditor needs to realize that not all the requirements related to Clause 7.6 may be applicable for such "equipment".

The auditor needs to understand how the organization performs process control and the impact that the information, obtained from using these types of "equipment", has on this process control.

When the impact is relevant, auditors should evaluate issues such as:

- How the organization validates that "the monitoring and measuring equipment" is consistent with the monitoring and measurement requirements.
- How the organization assures the information validity and the consistency of the results.
- The competence of those responsible for using "the monitoring and measuring equipment"

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. It is stressed that just because an organization does not have measuring equipment that needs to be calibrated does not mean that it can automatically exclude compliance with the whole of clause 7.6; to do so would require that it also does not do any monitoring or measurement (see

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particularly the first two paragraphs of clause 7.6) and that it does not use any monitoring or measuring equipment.

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

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.

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

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

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