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International Accreditation Forum

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ISO 9001 Auditing Practices Group *Guidance on:*

Monitoring and measuring resources

The following information is provided as guidance for auditing control of monitoring and measuring resources, and to assist in the evaluation of justifications for the non-application of clause 7.1.5 from the scope of an organization's quality management system. Guidance on "Measurement traceability" is provided in another ISO 9001 Auditing Practices Group paper.

1. Monitoring and measurement equipment

When auditing monitoring and measuring equipment, it is important for auditors to understand that the equipment supports monitoring and measurement methods that the organization has determined to be needed to ensure valid results.

It is also important to know the difference between "*monitoring*" and "*measuring*" :

- *monitoring* is to determine a status of something which implies observing, supervising, keeping under review; it can involve measuring or testing at intervals, especially for the purpose of regulation or control.
- *measuring* considers the determination of a value, e.g. a physical quantity, magnitude or dimension (using measuring equipment).

"Measuring equipment" is defined in ISO 9000 as "measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a *measurement process*".

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 resource (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).

The level of control depends on the intended use and determines whether or not measuring equipment needs to be calibrated or verified. The depth and degree of such control may vary, depending on the nature of processes, their outputs, 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 provision have been properly identified/specified and that the selected equipment “are suitable for the specific type of monitoring and measurement activities being undertaken”.

In the extent needed, 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.

2. Monitoring and measurement resources

Some organizations, mainly in the service sector (e.g. hotels, restaurants, education centers, consultants, public services), perform monitoring and measuring activities using surveys, examination papers, questionnaires, statistical methods, etc., due to the nature of their product. The applicability and validity of these methods has to be determined.

These types of monitoring and measurement resources should be controlled accordingly to ensure that they provide consistent means of monitoring and measurement of the processes, products and services, and customer satisfaction and ensure valid results. If an organization can demonstrate appropriate controls of such resources an auditor needs to realize that not all the requirements may be applicable for such resources.

3. Applicability of standard requirements

The organization needs to understand the impact of the information obtained from using these resources in the organization’s control of its QMS and its processes.

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

- How the organization validates that the monitoring and measuring resources are 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 resources

From the description above, the organization should be able to decide whether or not all or part of the relevant requirements may not be applicable. It is stressed that just because an organization does not have measuring equipment that needs to be calibrated does not mean that it doesn't automatically need to apply all the requirements for monitoring and measurement resources. To do so would imply that it also does not monitor or measure nor uses any monitoring or measuring resources.

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@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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