

International Organization for Standardization



International Accreditation Forum

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ISO 9001 Auditing Practices Group Guidance on:

Measurement Traceability

1. Background

ISO 9001, clause 7.1.5.2, requires the organization to ensure that "....when measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) calibrated or verified...
- b) identified..."
- c) safeguarded..":

It is important for auditors to seek demonstrable and objective evidence of such measurement traceability while auditing organizations. Traceability requires an established calibration hierarchy for measuring equipment.

Organizations should ensure that measurements performed to evaluate their products, services or equipment (e.g. for safety, quality, protection of health and the environment), or measurements performed by their own products, are traceable to SI units or to an agreed method of testing.

In testing it may not always be possible to achieve traceability to SI units; in such cases traceability may be achieved by using validated test methods, calibrated equipment and certified reference materials. In cases where an empirical value is being determined the measurement may just be traceable to the result of a specific test method being applied (e.g. fat content, colony count).

The requirements for measurement traceability and associated quality control procedures are specified for laboratories in ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* (see Sections 5.6 and 5.9).

Certification auditors should always seek to find objective evidence of such measurement traceability.

2. Implementation

Certification Body auditors should be aware that there are clearly defined requirements in regard to the acceptance of evidence of measurement traceability.

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"An item of measuring equipment shall be deemed to have traceability to internationally or nationally recognised standards of measurement when it has been calibrated by one of the following bodies and is of appropriate accuracy for the measurement in question:

- (a) Whether the calibration is traceable to an equipment calibrated in a metrology or calibration laboratory accredited for the measurement in question, by a national laboratory accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.
- (b) If the calibration is done is a National Metrology Laboratory then whether the NML is listed in the Appendix C of the Bureau International des Poids et Mesures (BIPM) database established under the Comite des Poids et Mesures (CIPM) Mutual Recognition Arrangement, for the measurement in question

To ensure that the measurements are covered by the calibration facility's scope of accreditation, the measurements must be reported on a certificate or report that contains the logo of one the above-mentioned authorities."

Auditors should be able to verify that measurements are traceable and accredited laboratories are used as far as possible.

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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