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.

The following statement from the ILAC/IAF JCCC should be considered while evaluating traceability:
“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 in 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 Comité 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.

Please access our websites at ISO 9001 Auditing Practices Group, or at Accreditation and Assessment Practices - IAF, where you can find information about ISO 9001 Auditing Practices Groups, download Introduction, the other ISO 9001 APG and AAPG papers.

Feedback from users is welcomed by APG/AAPG and will be used to determine the need for additional guidance documents, as well as for the revision of the current ones.

In case you wish to provide your feedback, the Group Secretary contact details are also available on these sites.

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