



国际标准化组织



国际认可论坛

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ISO 9001 审核实践组指南：

对测量结果溯源证明的探讨

1. 背景

ISO 9001的要求之一是对“监视和测量设备的控制”，其中的一个子要求是：“……测量设备应进行校准或验证，或两者兼而有之，按照规定的时间间隔，或在使用之前，对照能溯源到国际或国家标准的测量标准……”。

重要的是，审核员需要寻找可表明受审核组织对测量设备进行了溯源的客观证据，溯源需要建立校准层次结构。

组织应确保测量、评价他们的产品、服务或装备（安全，质量，健康和环境的保护）或由他们自己对产品进行测量，并可溯源至国际单位制（SI）或一个可接受的测试方法。

在测试中，可能并不总是能够实现溯源至国际单位制。在这种情况下，可通过使用验证测试方法、校准设备和标准物质来溯源。如某些经验的价值在于确定测量可能只是溯源到一个特定的测试方法被应用的结果（例如：脂肪含量，菌落计数）。

在ISO/IEC 17025《检测和校准实验室能力的通用要求》中指明了测量溯源性及相关的质量控制程序的要求（见标准的第 5.6 和 5.9）。

认证审核员应该始终坚持寻求找到这种测量溯源性的客观证据。

2. 执行

认证机构审核人员应该知道，在计量验收溯源的证据中，有明确的要求。

从ILAC（国际实验室认可合作组织）/IAF（国际认可论坛）JCCC 以下的语句，应考虑在评价溯源性期间：

“测量设备的一个项目，当它已由以下机构之一校准和对于拟议之中的测量来说其精度是适当时，应被视为已溯源至国际或国家认可的测量基准：

(a) 不论校准是溯源至一种计量校准设备，还是溯源至校准实验室认可的有关测量，通过国家实验室认可机构与国际实验室认可合作组织（ILAC）签署相互承认协议。

(b) 对于有疑问的测量，如果做这种校准的是一个国家计量实验室，则不论其是否是在国际度量衡办公室的附录 C 中所列出的国家测量实验室（National Measurement Laboratory），（国际计量局）数据库建立在科米特度量衡（国际计量委员会）互认协议。

为了确保测量范围覆盖鉴定合格的校准设备，测量结果必须出具书面的合格证书或包含一个上述权威机构的标志。”

审核员应该能够验证测量结果是可溯源的和尽可能地使用经认可的实验室。

（HXQC 宋治民编译，仅供参考）

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International Organization for Standardization

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ISO 9001 Auditing Practices Group

Guidance on:

Approach to Demonstration of Traceability* of Measurement Results

1. Background

One of the requirements of ISO 9001 is for the “control of monitoring and measuring equipment” and a sub-requirement is that “...measuring equipment shall be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards....”

It is important for auditors to seek demonstrable, objective evidence of such traceability for measuring equipment while auditing organisations. Traceability¹ requires an established calibration hierarchy.

Organizations should ensure that measurements performed to evaluate their products, services or equipment (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 Bodies 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 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