Traceability Overview

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ISO/IEC 17025 Calibration Laboratories

- 5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités). A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement.

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- 5.6.2.1.1 (cont'd) When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. ***The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification*** (see also 5.10.4.2).

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- **But how does that align with the following…**

- 5.10 Reporting the results
- 5.10.1 General

  The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

  The results shall be reported, usually in a test report or a calibration certificate (see Note 1), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

  In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

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- **And the following …**

- 5.10.2 Test reports and calibration certificates Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so
- 5.10.4 Calibration certificates 5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, ***where necessary for the interpretation of calibration results:***

  a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

  b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

  c) evidence that the measurements are traceable (see Note 2 in 5.6.2.1.1).

And then … just to cap it off….

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- **And ….**
- 5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

  When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

  When statements of compliance are made, the uncertainty of measurement shall be taken into account.

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- 5.6.2.1.1 NOTE 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an ***accreditation body logo*** from a calibration laboratory accredited to this International Standard, for the calibration concerned, ***is sufficient evidence*** of traceability of the calibration data reported.
- ***What about reference to "accreditation to ISO/IEC 17025" or a "statement"?***

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- 5.6.2.1.1 NOTE 4 The term ***"identified metrological specification"*** means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

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- 5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, ***unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result***. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.
- NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is ***the dominant factor***, the requirements should be strictly followed.

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NIST Website

Check out the NIST web site for
Traceability…supplemental materials

- http://ts.nist.gov/Traceability/SupplMatls/suppl_matls_for_nist_policy_rev.cfm

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NIST … “Traceability”

- "the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties."
- “It is important to note that traceability is the property of the result of a measurement, not of an instrument or calibration report or laboratory. It is not achieved by following any one particular procedure or using special equipment. “

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NIST … Who is Responsible?

- **Who is responsible for supporting claims of traceability?** The provider of the result of a measurement or value of a standard is responsible for supporting its claim of the traceability of that result or value. This is the case whether that provider is NIST or another organization.

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NIST … Who is Responsible?

- **Who is responsible for assessing the validity of claims of traceability?** The user of the result of a measurement or value of a standard is responsible for assessing the validity of a claim of traceability. However, as discussed … above, the provider is responsible for providing the necessary information that the user assesses.

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NIST Traceability … What is Needed?

- **What do I need to do to support a claim of traceability?** To support a claim, the provider of a measurement result or value of a standard must document the measurement process or system used to establish the claim and provide a description of the chain of comparisons that were used to establish a connection to a particular stated reference. There are several common elements to all valid statements or claims of traceability:
  - a clearly defined particular quantity that has been measured a complete description of the measurement system or working standard used to perform the measurement
  - a stated measurement result or value, with a documented uncertainty
  - a complete specification of the stated reference at the time the measurement system or working standards compared to it
  - an ***internal measurement assurance*** program for establishing the status of the measurement system or working standard at all times pertinent to the claim of traceability
  - an internal measurement assurance program for establishing the status of the stated reference at the time hat the measurement system or working standard was compared to

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NIST ..Internal Measurement Assurance Program

- An **internal measurement assurance program** may be quite simple or very complex, the level or rigor to be determined depending on the level of uncertainty at issue and what is needed to demonstrate its credibility. Users of a measurement result are responsible for determining what is adequate to meet their needs.

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NIST … NIST Report Numbers Sufficient?

- **Is a NIST Test Report Number sufficient evidence of traceability?** Test report numbers issued by NIST are used solely for administrative purposes. Although they often uniquely identify documents that bear evidence of traceability, test report numbers themselves do not address the issues listed in II.B.1 above, and should not be considered as the sole evidence of traceability.

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NIST … and Accreditation

- **Given that NIST operates the National Voluntary Laboratory Accreditation Program (NVLAP), does this mean that NIST stands behind claims of traceability made by NVLAP-accredited labs?** No. More specifically, laboratory accreditation, whether conducted by NIST/NVLAP or any other recognized accreditation body, is a finding of a laboratory's competence and capability to provide scientifically sound and appropriate measurement services within their scope of accreditation. Embedded in the process is an evaluation of the lab's ability to achieve and maintain traceability for the accredited services. Accreditation to ISO/IEC Guide 25, now replaced with international standard ISO/IEC 17025*: General requirements for the competence of testing and calibration laboratories*, determines that a laboratory has all of the necessary facilities, equipment, standards, procedures, uncertainty analyses, personnel, etc., which make it capable of providing traceable measurement results. Laboratory accreditation does not speak to the specifics of any individual measurement result but to the overall capability of a lab to provide the service.

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