Verifying Traceability to National and International Standards

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Abstract

Some nations recognize measurement results as "traceable" only if provided by accredited calibration laboratories. There are alternatives to the use of accredited laboratories in nations such as the United States, since the number of accredited calibration laboratories lags the need. If there are no accredited laboratories providing the calibration services needed (or if no accredited laboratory has a scope of accreditation that includes the services needed), accredited testing and calibration laboratories can obtain calibration services from non-accredited laboratories. However, the non-accredited laboratory will be challenged to validate its claims of traceable measurement results for its accredited testing and calibration laboratory clients.

This paper describes what non-accredited laboratories need to provide to their clients as evidence that their measurement results are traceable. It will also describe what evidence laboratories must collect from their non-accredited calibration service providers to assure themselves that the measurement results provided are traceable.

Introduction

In order to compare products and services in today's global economy, the measurement community is increasingly being challenged to

- Prove the veracity of the measurement data supplied to clients, and
- Determine the veracity and validity of the measurements obtained from others.

How do we know that a measurement is "true," "accurate," "precise," or "meets requirements?" See references [1] – [3]. Definitions of these terms have evolved over time, and the means for verifying these terms have evolved as well. "Traceability" of measurement results is one of the means for verification that has evolved [4] – [10] and is continuing to evolve as the need grows for proof of having met measurement requirements.

Traceability and Its Implications

The *International Vocabulary of Basic and General Terms in Metrology* (VIM) [11] defines traceability as 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."

We will use the VIM definition as the preferred one, because of its widespread use in the global marketplace. It is critically important to appreciate that the VIM definition is not restricted to physical and chemical measurement results, but may be appropriately applied to any type of measurement results. Because the definition can be applied broadly, it must be augmented by clarifying comments, notes and interpretative guidance.

A key factor in verifying the traceability of measurements to national and international standards is an understanding of the explicit and implicit requirements of the definition of traceability. The VIM definition makes it clear that traceability is

- The property of the result of a measurement or the value of a standard:
  - Not a measurement or an attribute of a national measurement institute (NMI) or other organization, and
  - Not a property of the instrument or of the standard.

The VIM definition requires not only

- An unbroken chain of comparisons,

but also implies

- An unbroken chain of uncertainties.

If we understand and accept the link between the unbroken chain of measurements and the unbroken chain of uncertainty statements, then

Any claim of traceability must be supported by a quantitative statement of uncertainty, the components of which include the uncertainties of all links in the chain of comparisons.

You must be assured that the quantitative uncertainty statement incorporates the uncertainties from the entire transfer process. Since this may be impractical or difficult in some fields of measurement and testing, further interpretive guidance has been needed, and some must still be developed. For example, construction-materials testing introduces significant issues with sampling from bulk lots [12]. Chemical testing introduces the issues of method dependency and validation [13]. It has been necessary to build a body of information on a case-by-case basis in each of these instances; see the guidance available at [14] and [15].

If an uncertainty statement is a fundamental requirement for establishing traceability of measurement results, then another very significant implication is the requirement for a measurement quality assurance system to assure the validity of the assigned uncertainty. The need for measurement quality assurance may be emphasized by the fact that neither a national measurement institute (NMI), such as the National Institute of Standards and Technology (NIST), nor any other calibration service provider can guarantee or certify the performance of a transfer standard except in the laboratory environment in which the calibration was performed. Assuring the performance of a transfer standard by checking it before and after sending it away for calibration is but one critical step in assuring that measurement and calibration processes are at an acceptable level of statistical control in the laboratory using the transfer standard. Failure to assure the integrity of the calibration process and the traceability link could lead to a large number of questionable measurements. The best way to avoid this consequence is a comprehensive measurement quality assurance system [16] – [18].

Some other critical implications of the VIM definition of traceability are:

- The acceptable "stated references,"
- Traceability of measurement results to the International System of Units, not to the NMI, and
- Repetition of transfers over time, that is, calibration intervals.

Acceptable Stated References

What is meant by "stated references?" Within the United States, stated references that will ensure traceability include [19]:

- U.S. national measurement standards maintained by NIST or, in the case of time standards, maintained by NIST and the U.S. Navy;
- National standards of other countries which are correlated with U.S. national standards through interlaboratory comparisons;
- Intrinsic standards based on well-characterized laws of physics, fundamental constants of nature, or invariant properties of materials. Use of intrinsic standards must be correlated with NMIs through interlaboratory comparisons;
- Fundamental constants with values evaluated by NIST;
- Standard Reference Materials and NIST-Traceable Reference Materials;
- Ratio types of measurements; and
- Comparisons to consensus standards, clearly specified and mutually agreed upon by all parties. These may also require verification through interlaboratory comparisons.

Traceability to the International System of Units

The ability to relate measurements to stated references, whether local, national, or international, implies the need for a single, uniform system of measurement units accepted and utilized on a global basis. The International System of Units (SI) meets this requirement. See the guide for U.S. use in [20]. Because the role of the NMI is to realize the SI, the traceability chain ends with the SI (modern metric system of units), not the NMI itself.

Calibration Intervals

Once traceability is established, it is critical to assure that uncertainty is at all times within the limits claimed because, as measurements are made over a period of time, it is fairly common for wear and tear on artifact standards to result in the drift of their measurement values. As previously indicated, this task is best addressed by a comprehensive measurement quality assurance system. Specifically, the task is to determine a suitable calibration interval. However, there are a number of factors and specifications which must be considered in determining the calibration interval of a standard at any level. For most laboratories and test facilities, the *NCSLI RP-1: Establishment & Adjustment of Calibration Intervals* [21], is a good guide and starting point. At the national and international levels, it is insufficient to sign mutual recognition agreements without also including timely characterizations, monitoring, interlaboratory comparisons, and/or recalibration of the appropriate national and international standards. In general these intervals are much longer than those of most laboratories, and may be as long as ten years. At the NMI level serious consideration must be given to the stringent requirement proposed by Belanger [6] that "measurements have traceability to designated standards if and only if scientifically rigorous evidence is produced on a continuing basis to show that the measurement process is producing measurement results (data) for which the total measurement relative to national or other designated standards is quantified."

The Larger Measurement Process

A single measurement at some place and time is part of a larger measurement process. Pictured below is the flow of measurements from national or international standards to the customer. Suppose you are a potential purchaser of a measurement; perhaps you are seeking a laboratory to calibrate your standards.

SI[NOTE]	International System of Units
	↓
NMI	"Realizes" the unit
	↓
	"Transfers" the measurement
	↓
	Intermediate laboratories?
	↓
	Intermediate standards?
	↓
Your calibration laboratory	Calibration laboratory's "primary" standards
	↓
	"Transfer" standards
	↓
You	Your standards

NOTE: In those instances for which measurement results cannot be traced to the SI, traceability to certified reference materials, such as NIST's Standard Reference Materials, and/or international consensus standards, such as Rockwell Hardness, is acceptable.

The NMI is responsible for conducting the physical experiments that constitute the definitions of the units (also known as "realization of the unit"), maintaining national and international artifact standards and other transfer standards, and beginning the measurement dissemination process.

NIST does a combination of both, depending on the parameter. The NMI may carry out its functions by

- realizing the definition of an SI unit (e.g., length),
- maintaining a national standard (e.g., vacuum),
- serving as the custodian of a national artifact (e.g., the kilogram),
- providing reference standards (e.g., Standard Reference Materials for hardness) and
- providing evaluated reference data which may include constants (e.g., see for example, the web site www.physics.nist.gov/CO2 for a database of the parameters in the photoionization of CO_2.)

In these cases, the NMI is responsible for checking the equivalency of its standards with those of its peers around the world through a series of international intercomparisons including those sponsored by the Consultative Committees of the International Bureau of Weights and Measures (BIPM). Dissemination services may be carried out by offering calibrations or by working closely with a system of laboratories that do most of the dissemination. NIST does a combination of both, depending on the parameter [22].

Ideally, intermediate laboratories should disseminate measurements that are well characterized by thorough uncertainty statements. In order to accomplish this, these laboratories must maintain their reference and working standards in good physical condition and internally monitor and document their performance with the use of statistical and quality control techniques.

These laboratories, however, also cannot guarantee the measurement results or the performance of a particular standard belonging to a client. They are responsible only for demonstrating the traceability of their own measurement results and maintaining that traceability when transferring measurements to their customers. The uncertainties they provide along with their measurements are, in the simplest instances, combinations of the uncertainties that their own measurement system experiences, together with the uncertainties obtained from the laboratory that calibrated their standards.

Customers are responsible for

- Understanding their own measurement processes and the uncertainties they produce,
- Caring for their standards, and
- Maintaining a suitable level of uncertainty to meet their own needs.

Customers are also responsible for determining that their measurement results are traceable.

The Role of Laboratory Accreditation

The laboratory accreditation process includes an external determination that a laboratory is capable of providing measurement results are “traceable.” Thus, the most accepted way to reassure yourself and your clients that your measurement results are traceable is to get your laboratory accredited and to use accredited laboratories for calibrating your standards.

But, what if your laboratory are not accredited? What if you have no accredited laboratory that can calibrate your particular standard or standards?

Whether you are someone looking for calibration services that are "traceable" or represent an unaccredited laboratory seeking to prove that the measurement results you provide are "traceable," your first responsibility is to determine

- What your clients require from you,
- What the agencies that regulate you require, and if accredited,
- What your accreditation body requires of you.

One or all of these organizations or individuals may require that the measurements you provide are "traceable." Usually accreditation bodies define what is meant by this term [23], [24]. In reality, neither the regulatory bodies nor your clients are as rigorous as accreditation bodies in their understanding and application of a requirement of traceability. Regulatory bodies and clients may, however, be *more* demanding in their requirements for documentary proof (see below "The Role of the NIST Number") even though this does not add value with respect to a claim of traceability.

Verifying Traceability of Transferred Measurements

The purpose of the following sections is to help laboratories, whether accredited or not, and customers, conduct a productive dialog with a measurement provider. When someone obtains measurements from a second or third party, to get a standard calibrated for example, several implied needs and criteria exist. If an accredited laboratory is needed, this may pose difficulties. The number of accredited calibration laboratories in the U.S. is still small. Currently, the International Laboratory Accreditation Cooperation (ILAC) recognizes only the private American Association for Laboratory Accreditation (A2LA) and the National Voluntary Laboratory Accreditation Program (NVLAP) (part of NIST) as accrediting bodies for calibration laboratories in the United States. These two bodies have accredited fewer than 400 calibration laboratories in the U.S. as of April, 2002. Even though the number is growing, growth is not uniform across all parameters and industry sectors.

The Role of the NIST Number

In the U.S. in the past, traceability was often demonstrated and verified by using the so-called "NIST Number." If you could show a NIST Number, it was accepted that your standards were traceable to NIST. Fortunately that situation has changed, spurred in large part by international competitiveness and the 1996 NCSLI Policy Statement [25] that a NIST number does not provide proof of a traceable measurement result. The growth of laboratory accreditation has led to better, well-defined methods of documenting traceability that can be verified by a third party. However, just to lay the matter to rest, it is important to reiterate what the NIST Number is and is not.

The NIST Number is assigned by the NIST Calibration Program as an administrative tracking number. By itself, a NIST Number is inadequate as proof of traceability. It does not tell a customer about a laboratory's quality system, reference standards, or measurement uncertainties. The NIST Number can be weighed, along with other evidence (such as a copy of the NIST report of test itself), to make a determination of the sufficiency of a path to SI units, derived units, or other national standards provided by NIST.

Guidance for Accredited Laboratories

If a laboratory is accredited, the following information needs to change hands with the measurement result:

- The name of the accreditor,
- A report that complies with ISO/IEC 17025 [26], and
- A statement that the work performed lies within the scope of accreditation.

Accreditation Body

Many organizations around the world accredit testing and calibration laboratories. The accreditor of a laboratory should be recognized by the customer's own customers, its industry, its regulators, and its international trading partners. Equally important, information about the accreditor will assure the customer that the laboratory is accredited to ISO/IEC 17025, not just registered to the ISO/IEC 9000 quality standard. Although accreditation involves meeting the relevant parts of the ISO/IEC 9000 quality standard, meeting ISO/IEC 9000 does *not* involve demonstrating technical competence. In addition, a company may be registered as conforming to the ISO 9000 quality standard, but its laboratory may not be covered by that registration, and the laboratory may not be accredited. *Always* check to be sure that the laboratory is accredited to ISO/IEC 17025 and that the accreditation is issued by a recognized accreditation body.

Report of Calibration or Test

This report must comply with ISO/IEC 17025 to meet the requirements of accreditation, but the customer may require guidance to understand all its parts. The uncertainties are as important as the reported measurement value. It is the uncertainties which determine the uses to which the customer can reasonably and reliably put the measurements. The change from ISO Guide 25 to ISO/IEC 17025 brought significant changes for testing laboratories that make it especially important to inquire about uncertainties.

Scope of Accreditation

A statement of the laboratory's scope is very important. Not all laboratories are accredited for all of their measurement capabilities. Just because a laboratory is accredited, it may not be accredited for the measurement in question. Even if it is accredited for the parameter in question, it may not be accredited over the full measurement range. A laboratory should verify that the requested measurement lies within its scope of accreditation, and customers should be careful to ask. It is important to remember that if the measurement lies outside an accredited laboratory's scope, that laboratory must be treated as unaccredited.

Guidance for Unaccredited Laboratories

If a laboratory you intend to use is not accredited, or its measurements lie outside its accreditation scope, you must perform the functions of an accreditation assessor in verifying traceability. Without this assessment, the traceability of your own results is unknown and unverifiable. How, then, do you verify that measurement results (say, calibration of your standard) supplied to you are "traceable?" (In the discussion below, we assume that the evaluator is competent in the measurement for which traceability is being evaluated.)

If we go back to the definition of traceability that we explored earlier, we can check on each requirement:

- An unbroken chain of comparisons to
- National or international references, with
- Known uncertainties at each transfer point.

This examination may be conducted

- By you of your calibration provider,
- By your customer of you, or
- By you of your own measurement process.

For ease of diagramming and discussion, we will assume these are questions you will ask of your own calibration laboratory. While intended to assist you with unaccredited laboratories, they are the same questions you might ask an accredited calibration laboratory or would expect your customers to ask you.

Questions to Ask

What standard or standards does your laboratory send out to be calibrated?
To whom are they sent -- to NIST or to intermediate laboratories up the chain?

The answers to these questions can assure you that the standards used to calibrate your standard are linked to SI units where possible. Some standards (often called derived standards) are based on more than one SI unit. An example is pressure which is based on mass, length, and the acceleration due to gravity. In this case, NIST offers calibrations of pressure standards, thereby providing the link back to the appropriate SI units for you. Another example, torque, also requires measurements of mass and length; but, NIST does not provide calibration services for this parameter. Therefore, a calibration lab providing measurements for torque has to trace back standards for both mass and length and show how it combines them.

What were the uncertainties reported to your laboratory for these standards?

These will become part of your uncertainty statement even if it is from the NMI. In order to evaluate the answer to this question, you must know what uncertainties you need. It makes no sense to either "under buy" or "over buy" uncertainty levels. Be sure you are getting suitable uncertainties. To do this, you will need to know how much uncertainty your internal measurements will add to the measurement process as well.

Were these standards measured by your laboratory before and after they were sent out?

This is important because:

- The standards will be out of the control of the calibration laboratory that sent them out;
- The calibration laboratory cannot guarantee that the measurement results that it determines for these standards will last until your laboratory gets the standards back;
- Standards can change their values in the process of shipping in either direction; and
- This information is an important part of your quality control system to be tracked over time.

This is one of the simplest precautions a laboratory can take to ensure that its standards do not change.

Are the standards that were sent out for calibration by the laboratory the same standards that were used by you to calibrate my standards?

If the answer to this question is no, maintenance of the "unbroken chain" is of paramount importantance. The laboratory must characterize the measurement uncertainty in the transfer from the standards sent out for calibration and the standards used to calibrate your standards.

- ***What were the methods of transfer from the laboratory's "primary" standards (the ones that were sent out) to the laboratory's "working" or "transfer" standards?***
- ***What were the components of uncertainty of this transfer?***

If the answer to the question is yes, as to whether the standards that were sent out for calibration are the same as those used to calibrate your standards, the uncertainty of the measurement result (and the components of this uncertainty) are more straightforward than when an intermediate transfer of measurements within your calibration laboratory is made.

What methods did the laboratory use to compare its standards to yours?

This question and the next are designed to explore the measurement system of your laboratory. You want to know how the measurements were made and you want to be certain that the environmental conditions in the laboratory support the claimed uncertainty statement.

What environmental controls did the laboratory employ?

The parameters controlled, and the level of control needed, will vary with the measurements being performed. For example, precise dimensional and mass measurements require stringent temperature and vibration control. For other parameters, such tight control may be less important [27].

What component uncertainties resulted?

Examining the components of an uncertainty statement gives you a window into the methods used and quality system of the laboratory performing the work.

What does the laboratory report as the total uncertainty for your standard?

This number is the starting point for your own uncertainty budget [29].

What quality control or quality assurance methods does the laboratory employ?

The quality assurance system provides some assurance that the laboratory will provide consistent measurements, and that it is tracking the behavior of all its standards – reference, working, and check. Some better-known methods are

- Use of a "second" standard or a "check" standard – A laboratory can
  - Measure its standards against each other before and after sending one of them out for calibration,
  - Measure the values of both standards over time, and
  - Insert a check standard into the measurement process periodically.

When the results of the comparisons are charted, all of these techniques produce valuable information not only for monitoring the performance of reference and working standards but also for setting and modifying recalibration intervals.

- Use of "primary" standard and "working" standard – This practice
  - Reduces wear and tear on the primary standard, and
  - Provides a duplicate standard to track sudden or gradual changes.

- Charting results of measurements and transfers using the standards, including
  - Internal transfers, between check standards, working standards, etc., and
  - External intercomparisons, such as
    - Interlaboratory comparisons, and
    - Proficiency tests.

These methods can provide valuable information about your measurement system and how well your results agree with your colleagues and customers. In particular, external comparisons are invaluable for assessing systematic biases (Type B errors) in your laboratory. A company with several laboratories or facilities might institute an internal interlaboratory comparison to be sure that all its products are uniform, regardless of source. Several companies within an industry sector might establish an interlaboratory comparison to assess the robustness of the whole industry's metrology efforts. Results of these comparisons can be reported anonymously in either case to encourage broad participation.

The Next Step

Having audited your unaccredited calibration or testing provider to assure yourself of the traceability of their measurement results, you might reasonably conclude that you are finished. But, you are not. It is necessary to determine that there is an unbroken chain of comparisons, and this requires you to determine if the calibrations obtained by your calibration provider resulted in traceable measurement results. If your calibration provider did not get his standards or instruments calibrated by an accredited laboratory, you must repeat the audit outlined above on his calibration provider.

Summary

These guidelines are presented to help you evaluate the measurements you receive from others and to help you meet your customers' needs for traceability. We have framed this discussion around ISO/IEC 17025. That should meet most of your needs. However, the change from specialized criteria to ISO/IEC 17025 is not proceeding uniformly in all industries and agencies. Although your customers and regulators make the final decision to accept your measurement results as traceable, you have opportunities to educate them as to what should constitute a traceable measurement result. Additional information on NIST's traceability policy can be found at http://www.nist.gov/traceability/

For an international perspective to traceability, see [29].

Accrediting bodies have guidelines for assessing traceability, especially for non-accredited laboratories. These can used by anyone, whether they are seeking accreditation or not. See especially those guidelines used by NVLAP [24] and A2LA [23].

References

1. Churchill Eisenhart, "Realistic Evaluation of the Precision and Accuracy of Instrument Calibration Systems," *Journal of Research of the NBS*, vol. 67C, pp.161-187, 1963.

2. P.E. Pontius, "Measurement Philosophy of the Pilot Program for Mass Calibration," *NBS Technical Note 288*, 1966.

3. P.E. Pontius and J. M. Cameron, "Realistic Uncertainties and the Mass Measurement Process, An Illustrated Review," *NBS Monograph 103*, 1967.

4. J.M. Cameron and H. Plumb, "Traceability – with Special Reference to Temperature Measurement," Society of Automotive Engineers, Report 690428, National Air Transportation Meeting, 1969.

5. J.M. Cameron, "Traceability?" *Journal of Quality Technology*, vol. 7, pp. 193-195, 1975.

6. Brian Belanger, "Traceability: An Evolving Concept," *ASTM Standardization News*, Vol. 8, pp. 22-28, 1980.

7. E.L. Garner and S.D. Rasberry, "What's New in Traceability," *Journal of Testing and Evaluation*, vol. 21, pp. 505-509, 1993.

8. C.D. Ehrlich and S.D. Rasberry, "Metrological Timelines in Traceability," *Journal of Research of the NIST*, vol. 103, pp. 93-105, 1998.

9. C. S. Brickenkamp, E. L. Garner and S. Dittmann, "Traceability, Measurement Uncertainty, and Accreditation" *NCSLI Annual Symposium and Workshop* 2001.

10. Brian Belanger, Stanley Rasberry, Ernest Garner, Carroll Brickenkamp, Charles Ehrlich, "Traceability: An Evolving Concept," *NIST Special Publication 958,* 2001.

11. International Vocabulary of Basic and General Terms in Metrology, International Organization for Standardization, Geneva, 1993.

12. United Kingdom Accreditation Service, "Calibration and Measurement Traceability for Construction Materials Testing Equipment", UKAS Publication ref: LAB210, Edition 2, October 2000.

13. Ellyn S. Beary, Ed., "Proceedings of the Workshop on Measurement Traceability for Clinical Laboratory Testing and In Vitro Diagnostic Test Systems," *NISTIR 6742*, 2001.

14. See the United Kingdom Accreditation Service web site: http://www.ukas.com/new_docs/news-publications.htm for many useful documents.

15. Contact the Asia Pacific Laboratory Accreditation Cooperation (APLAC) at aplac@nata.asn.au for a copy of "APLAC Policy and Guidance on the Estimation of Uncertainty of Measurement in Testing," Draft November 2001.

16. J.M. Cameron, "Measurement Assurance," *NBS Internal Report 77-1240*, 1977.

17. Brian Belanger, "Measurement Assurance Program Part I: General Introduction," *NBS Special Publication 676-I,* 1984.

18. Carroll Croarkin, "Measurement Assurance Programs Part II: Development and Implementation," *NBS Special Publication 676-II,* 1984.

19. National Conference of Standards Laboratories Laboratory Evaluation Committee, *Handbook for the Interpretation and Application of ANSI/NCSL Z540-1-1994,* 1996..

20. Barry N. Taylor, editor, "The International System of Units (SI)," *NIST Special Publication 330,* 2001.

21. *NCSLI RP-1: Establishment & Adjustment of Calibration Intervals,* 1996.

22. T.E. Gills, S. Dittmann, J.R. Rumble,Jr., C.S. Brickenakmp, G.L. Harris, and N. M. Trahey, "NIST Mechanisms for Disseminating Measurements," *NIST J.Res*, vol. 106, p. 315, 2001.

23. See the websites, http://www.a2la.org/pdfs/tracepol.pdf and http://www.a2la.org/a2la/waiver.htm for the American Association for Laboratory Accreditation's policies on traceability.

24. See the National Voluntary Laboratory Accreditation Program's traceability policy at the last page of http://ts.nist.gov/ts/htdocs/210/214/docs/final-hb150-2001.pdf. V.R. White, D.F. Alderman, C.D. Faison, editors, "National Voluntary Laboratory Accreditation Program Procedures and General Requirements," *NIST Handbook 150,*p. 60, 2001.

25. NCSL Position Statement 96-1, 07 May 1996

26. ISO/IEC 17025:1999, "General Requirements for the Competence of Testing and Calibration Laboratories," International Organization for Standardization, Geneva, 1999.

27. *NCSLI RP-7: Laboratory Design*, 1993.

28. Carroll Croarkin, Paul Tobias, "NIST/SEMATECH Engineering Statistics Handbook," http://www.itl.nist.gov/div898/handbook/ especially http://www.itl.nist.gov/div898/handbook/mpc/section5/mpc56.htm\

29. ILAC-G2:1994 "Traceability of Measurements," 1996 available at http://www.ilac.org/