TRACEABILITY of MEASURING EQUIPMENT in TESTING LABORATORIES

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Abstract

If a laboratory assessed obtain traceability from an outside laboratory (service provider) than the laboratory being assessed must show that the traceability is compliant with requirements. It is not the calibration facilities (service provider) responsibility, the responsibility is with the laboratory being assessed. A non-conformance (NC) will be raised when;

1. Traceability is obtained from an accredited laboratory, calibrations performed outside the scope and/or range of the accredited facilities schedule of accreditation,
2. Calibration certificate that does not make reference to accreditation, (by use of the SANAS Accreditation Symbol or equivalent),
3. Calibration was performed by personnel with no proven competency.
4. Calibration was performed by a non-accredited calibration laboratory.

If the laboratory is performing any tests or calibrations for legal purpose, then the calibrations can only be performed by an accredited facility, or the National Measurement Institute of South Africa (Act 18 of 2006).

The intention of this paper is to assist laboratories who are performing their own calibrations and intermediate checks **or** purchase calibration services for their standards, and to assist laboratories in communicate their requirements too the accredited calibration laboratories. and to analyse the results for compliance not only with their own but also with accreditation requirements.

1. Introduction

Over many years conducting assessments, I have been coming across certificates issued by accredited calibration laboratories, which do not bear the accreditation logo nor is a reference to the accreditation system made. Equipment is send to accredited calibration laboratories with no instructions or requirements specified by the user and no contract review ISO/IEC 17025:2005 section 4.4 [1] is done by the calibration laboratory. This topic was also addressed during the 2005 NLA conference [2].
The reasons for this are numerous; sometimes it is due to misinterpretation of ISO/IEC 17025:2005 and the SANAS requirements as documented in the “R” and “TR” series of documentation.

In addition, some test laboratories perform calibrations of its own equipment, which support their accreditation schedule however, they cannot provide evidence of a detailed procedure or competency this is due to not only lack of knowledge of the accreditation requirements but also misunderstanding of the terms “Traceability”, “Calibration”, “Verification” and “Validation”.

Sometimes it is due to other motives; the reasons for these are not part of this presentation.

2. Traceability & Calibration

Let us first see what the definitions for Traceability and Calibration in accordance to International Vocabulary of Metrology (VIM) are [3]

Metrological Traceability: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

Note1 *For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.*

Note 2 *Metrological traceability requires an established calibration hierarchy.*

Note 3 *Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.*

Note 4 *For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.*

Note 5 *Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.*

Note 6 *A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.*

Note 7 *The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).*

Note 8 *The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well as other concepts, such as 'sample traceability' or 'document traceability' or 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.*

Traceability chain: Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

Note 1 *A metrological traceability chain is defined through a calibration hierarchy.*

Note 2 *A metrological traceability chain is used to establish metrological traceability of a measurement result.*

Note 3 *A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.*

Calibration: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a

second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Note 1 *A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.*

Note 2 *Calibration should not be confused with adjustment of a measuring system, often mistakenly called "self-calibration", nor with verification of calibration.*

Note 3 *Often, the first step alone in the above definition is perceived as being calibration.*

What are the requirements of ISO/IEC 17025:2005(e) "General requirements for the competence of testing and calibration laboratories" [1] section 5.6.2 "Special Requirements?"

Section 5.6.2.1.1 states:- 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**.

Note *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.

Section 5.6.2.2.1 states:- 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.*

SANAS Document R79-02 [3] "Requirements for the Issue of SANAS Calibration Certificates" Section 6.1 states:-

Laboratories are encouraged to issue calibration certificates or reports bearing the accreditation symbol (logo) for calibrations covered by their schedule of accreditation. [4].

Any certificate or report issued without the SANAS accreditation symbol (logo) shall be viewed as having been issued outside of the accredited scope of the laboratory.

>>> **This statement is clear**<<<

Also

Therefore, there is **no reason** why an accredited calibration laboratories issues certificates that are not supported by the accreditation system, unless the calibration is done outside the requirements of ISO/IEC 17025:2005 and/or the accreditation system under which accreditation was granted.

There is also no reason why a customer should accept a calibration certificate that is not supported by the accreditation system.

3. Competence

As stated above if a laboratory receives results in compliance with the requirement or do not make reference to accreditation, (by use of the Accreditation Symbol or equivalent) then the results are deemed to have been issued outside of accreditation whether these results can from an accredited laboratory or not. Laboratory being assessed must show that the traceability chain has not been broken, as described in TR25-01 [5]. It is not their service provider's responsibility, but the responsibility of the laboratory being assessed.

In support of the ISO/IEC 17025:2005 requirement SANAS has issued Technical requirements documents TR 25-01 [5]. This document is to assist user laboratories (Cal and Test), to specify criteria for performing calibration and intermediate checks on equipment used in facilities accredited by the South African National Accreditation System (SANAS). This document is not intended for an accredited laboratory as a motivation to perform calibrations and reporting results in whatever format which do not comply with the requirements and/or to prove competency to its customers. Normally only a statement of traceability is made.

Section 3.1 states:- Equipment used, which could affect the validity of results in the laboratory, **must, where possible** be calibrated by an accredited calibration laboratory. Traceability of measurement and competence in performance of the calibration will be accepted by viewing the calibration certificate. This is the easiest route for an accredited facility to obtain traceability of measurement.

Section 3.2 states:- Should equipment be calibrated by a non-accredited calibration laboratory, the accredited organization using the equipment **is responsible** for providing sufficient evidence to confirm competent performance of the calibration and suitable traceability of measurement.

At least the following records shall be available:

* Calibration procedures;
* Proof of competence of the metrologist performing the calibration i.e. Training records;
* Proof of traceability of calibration;
* Proof that metrologist competently transferred the traceability to the instrument.

Section 3.3 states:- Proving this competent transfer of traceability may require an assessment by a metrologist appointed by SANAS. The accredited facility will bear the costs for this additional visit.

What does TR 25-01 section 3.2 imply:

The laboratory being asset must provide evidence of compliance with ISO/IEC 17025 sections	
Calibration **procedures**	5.4 "Test and Calibration Methods and Method Validation" **Including:** Estimation of Uncertainty of Measurements. Inter-Laboratory Comparison (PT/ILC) in compliance with SANAS R 48 covering the range and accuracy requirement.
Proof of **competence** of the metrologist performing the calibration i.e. Training records	5.2. "Personnel" **Including:** Training records, Calibrations performed, Declaration of Competency, Who declared the metrologist competent, Criteria for competency declaration. Participation in PT/ILC
Proof of **traceability**	5.6 "Measurement Traceability".

of calibration	**Including:** Certificates issue in compliance with SANAS R 79. Compliance with SANAS TR 25
Proof that **metrologist** competently transferred the traceability to the instrument	5.9 "Assuring the quality of test and calibration results" **Including:** Vertical assessments.

4 Verification & Validation

A few mainly test laboratories perform verification checks and call it incorrectly calibration.

Example:- Laboratories have a set of mass pieces, calibrated by an accredited laboratory. The laboratory perform what they say is a calibration of their balances at the points the laboratory is using in the test method only. This is neither a calibration nor verification as it is not in line with the requirements of ISO/IEC 17025:2005 and/or TR 25-01.

The definitions for verification and validation as described in the International Vocabulary of Metrology (VIM) [2] are;

Verification: Provision of objective evidence that a given item fulfils specified requirements

Example 1 *Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.*

Example 2 *Confirmation that performance properties or legal requirements of a measuring system are achieved.*

Example 3 *Confirmation that a target measurement uncertainty can be met.*

Note 1 *When applicable, measurement uncertainty should be taken into consideration.*

Note 2 *The item may be, e.g. a process, measurement procedure, material, compound, or measuring system.*

Note 3 *The specified requirements may be, e.g. that a manufacturer's specifications are met.*

Note 4 *Verification in legal metrology, as defined in VIML[53], and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.*

Note 5 ***Verification should not be confused with calibration**. Not every verification is a validation.*

Note 6 *In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.*

Validation: Verification, where the specified requirements are adequate for an intended use

Example 1 *A measurement procedure, ordinarily used for the measurement of X, may be validated also for measurement in Y.*

ISO/IEC 17025 states: Validation is the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5 Conclusion

5.1 When equipment is calibrated by an outside calibration laboratory (service provider)

Always

- ✓ Select an accredited calibration service provider who can comply with **YOUR** requirement.
- ✓ Ask if the service provider is accredited for the parameters and uncertainty that you require.
- ✓ Insist on a Certificate of Calibration bearing the accreditation Symbol or equivalent.
- ✓ When an accredited laboratory does not issue a certificate of calibration bearing the accreditation symbol or equivalent, ask WHY (for the record only) , and look for another service provider.
- ✓ Provide your calibration service provider **in writing** with
  - **YOUR** requirements
  - Model/Type of Equipment,
  - Accuracy or Uncertainty required,
  - Calibration interval, (An accredited calibration laboratory is not allowed to specify the next cal date except for legal purposes)
  - Calibrate in accordance with Manufacturer procedure and/or specific calibration points,
  - Any other requirements you may have.

Note! See also presentation M104 Test and Measurement Conference 2005 [2]

5.2 Laboratories who perform there own calibrations of equipment supporting there accreditation must comply with TR 25-01. The technical and competency requirements for a test laboratory must be the same as for an accredited calibration laboratory when performing in-house calibrations.

6 References

[1] ISO/IEC 17025:2005(e) General requirements for the competence of testing and calibration laboratories".

[2] M104 Test and Measurement Conference 2005 "**What Test Labs don't ask and Cal Labs don't tell"** by Tharien Klaumanns-Möller. This presentation can be down loaded from the NLA website http://www.nla.org.za/conferences/proceedings_archive/search_proceedings.php

[3] SANAS R79-02 Requirements for the issue of SANAS calibration certificates.

[4] ILAC-P8:07/2006 Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories.

[5] SANAS TR 25-01 Criteria for performing calibration and intermediate checks on equipment used in accredited facilities.

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