

# ***TRACEABILITY of MEASURING EQUIPMENT in TESTING LABORATORIES***

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*Seeing it once is better than being told a hundred times.*

*Old Chinese proverb: Zhou Chongguo (Han Dynasty)*

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:-

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



## Contract Review

- Equipment is send to accredited calibration laboratories with no instructions or requirements specified by the user and/or no contract review ISO/IEC 17025:2005 section 4.4 is done by the calibration laboratory.
- Certificates issued by accredited calibration laboratories, which do not bear the accreditation logo nor is a reference to the accreditation system made.
- 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
- “Validation”.

AND

Sometimes it is due to other motives.

The reasons for these are not part of this presentation.



Let us first see what the definitions for Traceability and Calibration in accordance to International vocabulary of metrology.

## **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

Note 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).



# 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.



# ISO/IEC 17025:2005(e)

## 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.



# ISO/IEC 17025:2005(e)

## 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

“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.

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 is a clear statement** <<<



# 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.

OR

- ❑ Why a customer should accept a calibration certificate that is not supported by the accreditation system.



## In support of the ISO/IEC 17025:2005

SANAS has issued Technical requirements documents TR 25.  
Applicable to all SANAS accredited facilities.

This document is to assist user laboratories (Cal and Test), to specify criteria for performing calibration and intermediate checks on equipment used in accredited facilities .

### AND NOT

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 prove competency to it's customs.



## SANAS Document TR 25

“Criteria for the Performing Calibration and Intermediate Checks on Equipment used in Accredited Facilities” 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.

## SANAS Document TR 25

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 the metrologist competently transferred traceability to the instrument.

## SANAS Document TR 25

What does section 3.2 imply

The laboratory being asset must provide evidence of compliance with  
ISO/IEC 17025 sections

### Calibration Procedures

Compliance with:-

Section 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.



# SANAS Document TR 25

What does section 3.2 imply

## *Proof of Competence of the Metrologist Performing the Calibration*

Compliance with:-

Section 5.2 “Personnel”

Including:-

- Training Records
- Calibrations Performed
- Declaration of Competency
- Who declared the Metrologist Competent
- Criteria for Competency
- Participation and results in PT/ILC



# SANAS Document TR 25

What does section 3.2 imply

## *Proof of Traceability of the Calibration*

Compliance with:-

Section 5.6 “Measurement Traceability”

Including:-

- Certificates issued in Compliance with SANAS R 79
- Compliance with SANAS TR 25



# SANAS Document TR 25

What does section 3.2 imply

*Proof that the Metrologist Competently Transferred the Traceability*

Compliance with:-

Section 5.9 “Assuring the Quality of test and Calibration results”

Including:-

➤ Vertical Assessments



## SANAS Document TR 25

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.



## 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, with no compliance with the Standard, SANAS TR documentation.

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.

The definitions for verification and validation as described in the International Vocabulary of Metrology (VIM) 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! **Verification should not be confused with calibration.** *Not every verification is a validation.*

# Validation

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.

International Vocabulary of Metrology (VIM) states:-

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  $Y$ .*



## Conclusion - 1

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

**Always.**

- ✓ Select an accredited calibration service provider who can and will comply with **YOUR** requirement.
- ✓ Ask if the service provider is accredited for the parameters, range 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.



## Conclusion - 2

Provide your calibration service provider in writing with YOUR requirements

- ✓ Model/Type of Equipment,
- ✓ Accuracy and/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. (turn around time, etc.)

Note! See also presentation M104 Test and Measurement Conference 2005. Laboratories who perform their own calibrations of equipment supporting their accreditation must comply with TR 25. The technical and competency requirements for a test laboratory are the same as for an accredited calibration laboratory when performing in-house calibrations.



## Conclusion - 3

When equipment is calibrated in-house

### The Laboratory Must.

- ✓ Comply with the requirements of TR 25 and any other SANAS applicable requirement as documents in the SANAS “R” & “TR” series of documentation.



**THANK YOU**

**QUESTIONS**



When know say so, if you don't know say so.  
That is real knowledge.

Old Chinese proverb:- Kong Qui (Confucius) 551-479 v.C