R10.12

Revision No : 03
Effective Date : 25.12.2015

Guidance on Traceability of Measurement Results

PREAMBLE

Reliable measurements are becoming ever more important for producing good quality products and services. Accordingly, normative documents stipulate that measurement results shall be traceable to national/international reference standards of measurement. The fact that the concept of traceability is described differently in various references and written standards may result in differing interpretations and misconceptions.

This Guidance defines the concept of "traceability of measurement results," describes how traceability could be obtained and demonstrated, and lays down TURKAK's requirements that shall be fulfilled to ensure traceability of measurement results. This Guidance is prepared for use by TURKAK-accredited testing laboratories, calibration laboratories, medical laboratories, inspection bodies, proficiency testing providers and reference material producers. **This Guidance includes and details the policies in ILAC P10:01/2013, ILAC Policy on the Traceability of Measurement Results.**

1. PURPOSE

The purpose of this Guidance is to regulate measures required to ensure and demonstrate the traceability of testing results, calibrations and measurements to national and international measurement standards. The policy established in this Guidance may also be applied to other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification).

2. SCOPE

This Guidance covers measurement, calibration, and validation of test and measurement instruments by conformity assessment bodies which have been accredited or have filed an application for accreditation.

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3. ABBREVIATIONS AND DEFINITIONS

3.1 Abbreviations:

APLAC : Asia Pacific Laboratory Accreditation Cooperation

BIPM : International Bureau of Weights and Measures (French: Bureau International des Poids et Mesures)

CMC : Calibration and Measurement Capability

CRM : Certified Reference Material

EA : European Co-operation for Accreditation

EN : European Standard

IAAC : Inter American Accreditation Cooperation

IEC : International Electrotechnical Commission

ISO : International Organization for Standardization

KCDB : Key Comparison Database

MLA : Multilateral Recognition Arrangement

MRA : Mutual Recognition Arrangement

RM : Reference Material

RMP : Reference Material Producer

SI : International System of Units (French: Système International d'Unités)

TS : Turkish Standard

NMI : National Metrology Institute

VIM : International Vocabulary of Metrology.

3.2 Definitions

3.2.1 Metrological traceability (VIM 3 clause 2.41)

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: Clause 2.41 states that 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."

In ISO/IEC 17025:2005 and ISO 15189:2007 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this Guidance.

3.2.2 Metrological traceability chain (VIM 3 clause 2.42)

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

3.2.3 Metrological traceability to a measurement unit (VIM 3 clause 2.43)

Metrological traceability where the reference is the definition of a measurement unit through its practical realization.

Note: The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

3.2.4 National Metrology Institute

National Metrology Institutes (NMIs) and Designated Institutes (DIs) maintain standards in countries (or regions) all over the world. Throughout this Guidance, the term "National Metrology Institute" is used to cover both National Metrology Institutes as well as Designated Institutes.

3.2.5 Calibration Providers

Recognised calibration provider:

An NMI whose service is suitable for the intended need and is covered by the CIPM MRA (services of NMIs under CIPM MRA accessible through BIPM KCDB) or a calibration

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laboratory, with suitable accreditation scope for intended use, accredited to ISO/IEC 17025 standard by an accreditation body which is covered by the ILAC Arrangement or by Regional Arrangements (EA, APLAC, IAAC etc.) recognised by ILAC.

Non-recognised calibration provider:

Calibration providers other than the above.

Note: Conformity Assessment Bodies (CAB) that perform internal calibrations (also known as "In-house" calibrations) should not be evaluated in the context of recognised/non-recognised provider. Calibrations performed by a CAB in order to establish metrological traceability for its own activities, and which are not a part of the CAB's scope of accreditation (internal calibrations), are assessed according to ISO/IEC 17025, this guide and other technical documents.

4. APPLICABILITY

The policies and requirements in this Guidance apply to accreditation processes where the following standards are used as criteria:

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ISO 15189 Medical laboratories – Particular requirements for quality and competence
- ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing
- ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services
- ISO Guide 34General requirements for the competence of reference material producers.

5. POLICY

5.1 Traceability and Calibration Policy

Turkish Accreditation Agency's policy on calibration of measurement instruments and traceability of measurement results is described below. This policy is established to fulfil the requirements defined in TS EN ISO/IEC 17025 clause 5.6.

1. An organization using external calibration services shall use a recognised calibration provider for the tests, calibrations within the scope of its accreditation, and the calibration of equipment which contributes significantly to the measurement results in order to fulfil the requirements defined in TS EN ISO/IEC 17025 clause 5.6; in the absence of such a provider and in necessary

and specific circumstances, a non-recognised calibration provider who has demonstrated its competence.

2. Where an organization using external calibration services has used non-calibrated equipment in tests, calibrations and measurements within the scope of its accreditation, it shall demonstrate to TURKAK that the equipment in question contributes insignificantly to the uncertainty of measurement results.

3. An organization using external calibration services shall have available the records on the competence of the calibration provider.

4. An organization using external calibration services shall adopt a proactive approach to fulfil the requirements defined in TS EN ISO/IEC 17025 clause 5.6.

5. An organization using external calibration services shall furnish TURKAK with justification where it has to use a non-recognised calibration provider. Economic reasons do not constitute justification to abandon the use of a recognised calibration provider. Where it is demonstrated that competence requirements are fulfilled to this Guidance, the use of a non-recognised calibration provider is allowed.

6. The non-recognised calibration provider in question shall be assessed for its relevant calibration and measurement capabilities (CMCs) by the laboratory using external calibration services. The laboratory using external calibration services shall prove that the non-recognised calibration provider is competent to perform calibrations that comply with the relevant clauses of TS EN ISO/IEC 17025 Standard as indicated in Annex A, and other requirements as defined in Annex B.

7. An organization using external calibration services shall demonstrate the evidence for the competence of the non-recognised calibration provider to TURKAK during the accreditation process. TURKAK shall include competent assessor(s) in the audit team to that end, and assess the documented evidence and records demonstrating the competence of the non-recognised calibration provider used by the laboratory being audited.

8. According to the clauses of R20-18 TURKAK Marked Laboratories Test and Calibration Reports, a calibration laboratory accredited by TURKAK pursuant to the aforesaid document shall use the accreditation symbol in its calibration certificates/reports. Where a calibration certificate/report issued by a calibration laboratory accredited by TURKAK does not carry the accreditation symbol under the said document, that certificate/report cannot be accepted as evidence of traceability.

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As indicated in General Requirements of ILAC P8 policy document, only certificates/reports that have the accreditation symbol/logo/mark may fully enjoy the recognition accorded by the ILAC MRA and Regional Arrangements (EA, APLAC, IAAC etc.) recognised by ILAC.

Therefore, calibration certificates issued by calibration laboratories accredited by an accreditation body other than TURKAK, which is covered by the ILAC Arrangement or by Regional Arrangements (EA, APLAC, IAAC etc.) recognised by ILAC shall have the accreditation mark or the reference information to accreditation status in order for such certificates to constitute an evidence of traceability. Where the accreditation symbol is missing, it is the responsibility of the organization using external calibration services that the calibration in question has been provided by an organization accredited in the relevant scope.

9. In order to maintain confidence in the calibration status of the equipments, CABs should consider ILAC-G24:2007 / OIML D 10:2007 (E) Guidelines for the Determination of Calibration Intervals of Measuring Instruments document.

10. The clauses of this Guidance apply also to traceability in respect of organizations using internal calibration.

6. SELECTION OF A CALIBRATION PROVIDER AND DOCUMENTATION

The documentation on the selection and competence of the external calibration provider shall as a minimum include the following.

6.1 Where a Recognised Calibration Provider is used

The concept of recognised calibration provider is explained in clause 3.2.5.

6.1.1 The organization using external calibration services shall identify the calibrations conforming to the requirements defined in TS EN ISO/IEC 17025 clause 5.6 with appropriate measurement uncertainties for the needed measurement services and ranges.

6.1.2 Calibration certificates shall be verified to fulfil the requirements defined in TS EN ISO/IEC 17025 clause 5.6.

Note: The scope of such a verification may include the examination of a database on the Web, assessment of the documentation on accreditation and reviewing the scope of the calibration laboratory.

6.2 Using a non-Recognised Calibration Provider where a Recognised Calibration Provider is not available

Where a recognised calibration provider is not available, the laboratory may not be required to conduct an audit to establish the competence of the non-recognised calibration provider.

However, the calibration capabilities of the non-recognised calibration provider shall be assessed, documented and recorded.

In order to demonstrate its competence, a non-recognised calibration provider shall present documents and records specified in Annexes A and B; and fulfil the requirements in the Check List in Annex B.

6.2.1 The laboratory shall provide the calibrations conforming to the requirements defined in TS EN ISO/IEC 17025 clause 5.6 with appropriate measurement uncertainties for the needed measurement services and ranges.

6.2.2 The laboratory shall ensure that the calibration certificate issued by the calibration provider shall conform to TS EN ISO/IEC 17025 clause 5.10.

6.2.3 The laboratory shall obtain and keep the following documents and records:

- Records that a laboratory using non-recognised calibration provider has obtained such service through researching according to the hierarchy in Annex C.
- Documentation of the information and evidence of the competence of the non-recognised calibration provider as obtained using the check list in Annex B.
- Records on the traceability of the standard equipment used by the non-recognised calibration provider.
- Calibration procedures used by the non-recognised calibration provider including those prepared by itself or externally published methods.
- Minimum documents and records in Annex A demonstrating the technical competence of the non-recognised calibration provider and the claimed metrological traceability.

7. TRACEABILITY REQUIREMENTS IN THE ABSENCE OF DIRECT TRACEABILITY TO SI UNITS

In some cases, traceability to SI units may not be possible. Then, it shall be stated that the requirements in clause 6 of this Guidance cannot be met, along with reasons. As TS EN ISO/IEC 17025 clause 5.6.2.1.2 states that

> *There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:*
>
> - *the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;*
> - *the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.*

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Participation in a suitable programme of inter laboratory comparisons is required where possible.

Thus, it is the responsibility of the organization using external calibration services to select a method to fulfil the requirements of this clause. The organization using external calibration services shall provide appropriately documented evidence.

8. TRACEABILITY REQUIREMENTS UNDER THE ILAC ARRANGEMENT IN TESTING

The ILAC Arrangement in testing covers both testing laboratories accredited to TS EN ISO/IEC 17025 as well as medical laboratories accredited to TS EN ISO 15189. Considering TS EN ISO/IEC 17025 clause 5.6.2.2.1 stipulating that

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.

and TS EN ISO 15189 clause 5.6.3 stipulating that

A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference.

the following requirements shall be taken into account:

a) If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the requirements in clauses 6 and 7 of this Guidance shall be taken into account.

b) If a calibration is not a dominant factor in the testing result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributes little (insignificantly) to the measurement result.

Considering TS EN ISO/IEC 17025 clause 5.6.2.2.2 stipulating that

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> *Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see clause 5.6.2.1.2).*

and TS EN ISO 15189 clause 5.6.3 et seq. stipulating that

> *Where none of these are possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:*
>
> *a) participation in a suitable programme of inter-laboratory comparisons;*
>
> *b) use of suitable reference materials, certified to indicate the characterization of the material;*
>
> *c) examination or calibration by another procedure;*
>
> *d) ratio or reciprocity-type measurements;*
>
> *e) mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned;*
>
> *f) documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.*

the requirements in clause 7 of this Guidance shall be taken into account.

9. REQUIREMENTS FOR TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMs) AND CERTIFIED REFERENCE MATERIALS (CRMs)

TS EN ISO/IEC 17025 traceability requirements in relation to reference materials include:

> *5.6.3.2 Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.*
>
> Note 1: Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.
>
> Note 2: At present, the ILAC Arrangement does not cover the accreditation of reference material producers (RMPs).

TURKAK's policy on traceability in relation to reference materials is:

9.1 The values assigned to CRMs produced by NMIs covered by CIPM MRA and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34 are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).

9.2 The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

9.3. The majority of RMs and CRMs produced by other RMPscan be considered as critical consumables.The laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required by clause 4.6.2 of TS EN ISO/IEC 17025 Standard and TS EN ISO 15189 Standard.

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ANNEX A

(MANDATORY)

The following minimum documents and records shall be presented for the technical competence of the laboratory and the claimed metrological traceability:

- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Documentation for traceability of measurements (5.6)
- Documentation for assuring the quality of calibration results (5.9)
- Documentation for competence of staff (5.2)
- Documentation for accommodation and environmental conditions (5.3)
- Audits of the calibration laboratory (4.6.4 and 4.14)

Other documentation and records stipulated in this Guidance shall also be presented to TURKAK.

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ANNEX B

(MANDATORY)

Checklist for the assessment of the calibration and traceability of measurement and test instruments of a laboratory

(Caution: Affirmative answers in the form of mere "yes" to the following questions may fail to ensure that the requirements in this Guidance are met).

1 General

All requirements in clauses 6.1 and 6.2 of this Guidance, whether or not mentioned in this questionnaire, shall be fulfilled.

The assessor (laboratory staff / internal auditor or TURKAK assessor) using this Control List shall be knowledgeable and specialised in the relevant measurement instrument, metrology and calibration.

2 Appropriate Calibration of a Measurement Instrument

2.1 Have appropriate calibration procedures been established for each measurement instrument?

- Is there conformity in consideration of the uncertainty of the measurement equipment?
- Is there conformity in consideration of the contribution of the measured magnitude to the test result?

2.2 Has a test/measurement procedure been established that can be conducted appropriately in reference to natural constants for the measurement equipment (e.g. defined wave lengths)?

3 Calibration Provider

3.1 Is the calibration performed by a recognised calibration provider assigned or accredited for the need?

3.1.1 Is it a national metrology institute which is covered by the CIPM MRA and whose CMC information is recorded in the BIPM KCDB database?

3.1.2 Is it a recognised, accredited calibration provider?

(If "yes", no further inquiry is needed).

3.2 Is calibration performed by an organization other than those listed in clauses 3.1.1 and 3.1.2?

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3.2.1 Is calibration performed by a non-recognised calibration provider?

(If "yes", all requirements in clause 6.2 and the following requirements shall apply).

4 Equipment and Infrastructure Used in Calibration

4.1 Is it known that reference standard instruments and instruments of working standard exist for the magnitudes measured by and the measurement ranges of all measurement and test instruments subject to calibration?

4.2 Are these standards referring in an unbroken chain to the national and/or international standards as established by documented calibration certificates directly or indirectly? Is this made clear by labelling/marking for each measurement magnitude and working range?

4.3 Are instruments used in calibration defined?

4.4 Are calibration methods or procedures described?

4.5 Is the calibration procedure explained step by step?

4.6 Are environmental conditions required during the calibration described?

4.8 Are environmental conditions required during the calibration observed and recorded?

4.9 Is a procedure established and implemented to calculate the measurement uncertainty of the calibration operation?

4.10 Are re-calibration periods established for the relevant instruments of the calibration provider and is a schedule for calibration made?

4.11 Does the calibration provider fulfil the requirements in ISO/IEC 17025 clause 5.5.2?

4.12 Are reference materials used in calibration?

4.12.1 Are reference materials certified?

4.12.3 Do such certificates have an uncertainty value?

4.12.4 Is computer-aided calibration performed?

4.12.5 Has the software used been validated?

4.12.6 What is the method of validation?

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5 Responsibilities for Calibration of Measurement Equipment

5.1 Are users of the measurement equipment held accountable for the calibration status of the instruments?

5.2 Is possible to demonstrate the competence of the calibration staff to use the relevant instruments and methods?

5.3 Is new equipment calibrated prior to using?

5.4 Is there a follow-up and alert system to re-calibrate the equipment whose calibration period has expired?

5.5 Are there regulations requiring the calibration provider to have traceable calibration performed for the reference standards and working standards?

5.6 Are there regulations to ensure reliability of the calibration software?

6 Documentation

6.1 Are there records of any research to identify a recognised or non-recognised calibration provider for calibration needs?

6.2 Has the technical competence of the laboratory staff assigned to assess the non-recognised calibration provider been documented? Are they adequate?

6.3 Has the metrological traceability of the standard equipment used for calibration been documented and approved?

6.4 Has the traceability of measured magnitudes and measurement ranges been documented?

6.5 Has the compliance with calibration periods checked?

6.6 Have the operations identified for which the relevant instrument needs to be calibrated prior to measurements and has the instrument been accordingly labelled?

6.7 Are calibration results including environmental conditions documented and filed? Can calibration operators access such information?

6.8 Are calibration labels used as a visual means of information on conformity/non-conformity of the control system for the measurement instruments?

6.9 Are seals on the instruments to prevent tampering checked?

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6.10 Are there procedures to assess and calculate the measurement uncertainty? Do they meet the requirements in ISO/IEC 17025 clause 5.4?

6.11 Is there documentation to check the validity of estimated values of measurement uncertainty? Are these values conformant?

6.12 Are calibration results and associated uncertainties recorded?

6.13 Is participation ensured in inter-laboratory comparisons to verify the uncertainty values?

ANNEX C

(MANDATORY)

Where a non-recognised calibration provided is used, an organization using external calibration services shall observe the following hierarchy:

1) A NMI which is signatory to the CIPM MRA but not included in the KCDB database for the intended calibration service. In such case, the references used by such NMI for the intended calibration service shall be traceable to a recognised calibration provider.

2) A laboratory which is accredited to ISO/IEC 17025 Standard by an accreditation body signatory to the Recognition Arrangement with at least one of EA, ILAC, APLAC or IAAC, but does not provide the intended calibration service in the scope of accreditation. In such case, the references used by such laboratory offering calibration service shall be traceable to a recognised calibration provider.

3) A non-recognised calibration provider whose references used in the intended calibration service are traceable to a recognised calibration provider. Such traceability may be obtained through several stages.

4) A non-recognised calibration provider which claims traceability to national standards shall demonstrate that such national standards fulfil the properties of primary standards for the realization of SI units. The laboratory shall maintain records that the traceability chain established in this way meets the requirements of the standard.

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