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TPS 41

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UKAS Policy on Metrological Traceability

Contents

Changes since last edition

No major changes have been introduced in this version of TPS 41. The document has been amended in order to update references to key documents.

1. Introduction

1.1 This document describes the UKAS policy with regard to the metrological traceability requirements contained within ISO/IEC 17025 [1] and ISO 15189 [2]. This policy may also be applied to other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification). This document also encompasses and amplifies the policies contained within ILAC document ILAC-P10 [3]. A glossary of terms is included in Section 5.

1.2 Metrological traceability is required for all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling. Calibration may not be required for subsidiary equipment where the result is unaffected or where the equipment is monitored by calibrated equipment during the measurement.

1.3 For calibrations performed by an organisation in order to establish metrological traceability for its own activities, and which are not a part of its scope of accreditation, the policy in Section 4 is applicable. Such internal calibrations are sometimes known as “in-house” calibrations.

1.4 The definition of metrological traceability contained within the Vocabulary of Metrology (VIM) [4] is as follows:

1.4.1 *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.*

1.4.2 Implicit within this definition is that each calibration certificate in the traceability chain must contain a statement of uncertainty (or, exceptionally, a statement of compliance with an identified specification) otherwise the results presented therein do not exhibit metrological traceability. Uncertainty evaluation is normally conducted in accordance with the Guide to the Expression of Uncertainty in Measurement (the GUM) [5] or its interpretative documents such as UKAS M3003 [6]. Acceptable sources of traceability are described in Section 2.

1.4.3 It is further noted that metrological traceability is an attribute of the *result* of a measurement. Consequently, commonly used expressions such as “the equipment is traceable” are incorrect. Only if equipment is used correctly by trained staff in a suitable environment to defined procedures, is properly maintained, is itself subject to a calibration of suitable coverage and is subject to an appropriate level of intermediate checks and quality control can the results be demonstrated as being metrologically traceable.

1.5 In ISO/IEC 17025 and ISO 15189 the term “traceability” is equivalent to the VIM’s “metrological traceability”. To avoid repetition, the term “traceability” is used henceforth in this document.

2. Sources of Traceability

2.1 For equipment and reference standards where calibration is required, the following are acceptable sources of traceability:

2.1.1 A national measurement institute (NMI), or a designated institute, whose service is suitable for the intended need and is covered by the CIPM MRA for those services. Institutes included in the CIPM MRA, including quantities and CMCs, can be viewed at http://www.bipm.org/en/cipm-mra/participation/signatories.html.

2.1.2 A calibration laboratory whose service is suitable for the intended need and which is accredited for those services by an Accreditation Body that is included in the ILAC Arrangement or by Regional Arrangements recognised by ILAC. The schedules for UKAS accredited calibration laboratories can be viewed at www.ukas.com.

2.1.3 It is emphasised that the extent of the calibration obtained should be sufficient in terms of quantities and coverage to demonstrate properly the performance of the equipment, otherwise traceability of results may not be assured.

2.2 There may be situations where it is not possible to obtain calibrations for the required quantities from any of the sources described above. In such cases, the following sources of traceability may be acceptable providing additional assurance is obtained as described in 2.2.4.

2.2.1 A national measurements institute, or a designated institute, whose service is suitable for the intended need but is not covered by the CIPM MRA.

2.2.2 A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.

2.2.3 The choices in 2.2.1 and 2.2.2 shall not be made on purely economic grounds (such as the cost of using a particular organisation) or on logistical grounds (such as the need to employ an overseas organisation to obtain traceability). It is a last resort if other routes are unavailable.

2.2.4 Furthermore, these choices are not services that have been subject to peer review or recognised accreditation. Consequently, an organisation using such services must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. UKAS will assess such evidence and the organisation's ability to evaluate it. Such evidence may include, but is not limited to, the following.

a) Copies of the technical procedures and records of calibration method validation
b) Procedures for estimation of uncertainty and copies of the associated uncertainty budgets
c) Documentation for traceability of measurement results
d) Evidence of staff competence and authorisation
e) Documentation for assuring the validity of calibration results and the associated outcome
f) Documentation for accommodation and environmental conditions
g) On-site audit of the calibration laboratory

2.2.5 Evidence of traceability will only be accepted for the specific procedures and quantities audited, as traceability for any other measurement services offered by the organisation has not been assessed.

2.3 The UKAS policy for traceability for reference materials is as described in ILAC-P10 [3], i.e.

a) The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its scope of accreditation to ISO 17034, are considered to have established valid traceability;
b) The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability;
c) The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the organisation shall demonstrate that each RM or CRM is suitable for its intended use as required by ISO/IEC 17025 or ISO 15189.

3. Maintenance of Traceability

3.1 In order to maintain traceability on a continuous basis, reference standards and measuring equipment shall be subject to further calibrations on an ongoing basis, hence the establishment of a calibration programme is necessary. The intervals between calibrations will depend on various factors, including but not limited to:

a) The measurement uncertainty required
b) The past history of the equipment, including the results of calibrations and frequency of any necessary maintenance
c) The frequency of use of the equipment
d) The frequency of cross-checking against other equipment or of intermediate checks
e) The recommendations of the manufacturer
f) The environmental conditions to which the equipment is exposed, including any effects due to transportation

3.2 When a fresh calibration has been obtained the data provided should be reviewed in order to confirm that the declared performance is still met. It may be necessary to reconsider the calibration interval or the suitability of the equipment in accordance with the outcome of such a review. Furthermore, in the case of a calibration laboratory, the CMCs may be affected; in such cases UKAS shall be informed.

3.3 Further information regarding calibration intervals is available in ILAC-G24 [7].

4. In-House Calibrations

4.1 It is recognised that organisations accredited for calibration, testing, inspection or proficiency testing activities may choose to carry out some calibration activities in-house to support their measurement activities rather than seek the services of an external accredited laboratory.

4.2 It is essential that in-house calibration activities in support of accredited measurement activities are carried out competently and provide appropriate traceability of results.

4.3 Organisations carrying out in-house calibration are required to ensure that the traceability of their calibration results meet the requirements of this document and the relevant requirements of ISO/IEC 17025 or ISO 15189.

4.4 If the organisation has established that the associated uncertainty from an in-house calibration makes an insignificant* contribution to the expanded uncertainty of a test result then less stringent requirements for traceability, (e.g. a manufacturer's certificate) may be acceptable. In all cases the organisation should ensure that the equipment used provides the measurement uncertainty needed.

* In this case, "insignificant" is defined as "not changing the value of the expanded uncertainty by more than 5 %".

4.5 In some cases, the calibration of supporting equipment may be included in the procedure for a specific test or calibration; this situation is sometimes referred to as "calibrate before use". In such cases, the procedure shall contain sufficient information for proper conduct of the calibration. The traceability criteria in TPS 41 apply to such calibrations and the equipment should be labelled "calibrate before use", or similar.

4.6 It is reasonable to expect that in-house calibrations are subject to the same level of technical rigour that would be obtained if an external accredited laboratory or recognised NMI were used. To this end, the following shall be in place:

a) a suitable environment in which to conduct the calibration;
b) competent and authorised personnel to both conduct the calibrations and to carry out any necessary checks;
c) reference standards, certified reference materials or reference measuring instruments that provide traceable results with suitable measurement uncertainties;
d) a controlled and documented procedure for each type of calibration;
e) a means of recording, analysing and reporting the data and results of any calculations;
f) a suitable level of quality control activities;
g) a process for calculating the measurement uncertainty for each calibration.

4.7 Organisations carrying out in-house calibrations in support of their accredited activities are required to provide details of these calibrations to UKAS. These details will normally include information regarding the methodology involved, the traceability arrangements and the uncertainty budgets and UKAS will normally request such information for initial assessments, reassessments and extensions to scope. Furthermore, is important that UKAS is notified of any changes to these details as soon as they occur. UKAS will use this information to ensure that the appropriate expertise is included in the assessment team to assess these activities.

4.8 Wherever practical the assessment of in-house calibrations will be covered as part of the traceability and calibration aspects within normal assessment/surveillance activities. Where significant additional assessment time or additional assessors are required, there will be an additional cost associated with this activity.

4.9 Specialist calibration assessors will be used if the in-house calibration is outside the area of expertise of the assessment team already involved in the assessment of the accredited activities. The assessment procedures used will include document review and on-site witnessing as appropriate. On-site witnessing of in-house calibration activities can be expected at least at initial assessment and at reassessment visits.

4.10 The ability to perform in-house calibrations will not be included in the published schedule of accreditation. UKAS will, however, retain records of the in-house calibrations assessed.

4.11 An organisation may be required to participate in a measurement audit programme for the in-house calibration activities if it is determined that:

a) The extent of internal calibrations is such that a significant proportion of the accredited activities is strongly dependent on them;

b) an assessment has identified concerns about the performance of, or deficiencies in, the conduct of in-house calibrations;

c) the organisation has identified nonconforming work in its accredited activities (e.g. poor performance in a proficiency test) and it is reasonable to suspect that the in-house calibration may have contributed to the poor performance.

5. Glossary

BIPM	Bureau International des Poids et Mesures (International Bureau of Weights and Measures)
BIPM KCDB	The Key Comparison Database of the BIPM; see http://kcdb.bipm.org/
CIPM	Comité International des Poids et Mesures (International Committee for Weights and Measures)
CIPM MRA	The CIPM Mutual Recognition Arrangement; see http://www.bipm.org/en/cipm-mra/
CMC	Calibration and Measurement Capability
CRM	Certified Reference Material
IFCC	The International Federation of Clinical Chemistry and Laboratory Medicine
ILAC	The International Laboratory Accreditation Cooperation
JCTLM	The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine
NMI	National Measurements Institute (or National Metrology Institute)
RM	Reference Material
RMP	Reference Material Producer
UKAS	The United Kingdom Accreditation Service

6. References

[1] ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

[2] ISO 15189:2012, Medical laboratories - *Particular requirements for quality and competence*

[3] International Laboratory Accreditation Cooperation, ILAC P10:01/2013, *ILAC Policy on the Traceability of Measurement Results (under revision)*

[4] Joint Committee for Guides in Metrology, JCGM 200:2012, *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*

[5] Joint Committee for Guides in Metrology, JCGM 100:2008, *Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)*

[6] United Kingdom Accreditation Service, M3003, *The Expression of Uncertainty and Confidence in Measurement*, Edition 3, November 2012 *(under revision)*

[7] International Laboratory Accreditation Cooperation, ILAC-G24:2007, *Guidelines for the determination of calibration intervals of measuring instruments*

Additionally, several guidance documents on the application of ISO/IEC 17025 calibration and traceability requirements for particular items of equipment and types of measurement are available from the UKAS website, www.ukas.com (see *Publications List*).