



TPS 57

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UKAS Policy on Selection and Use of Reference Materials

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CHANGES SINCE LAST EDITION

1 INTRODUCTION

- 1.1 ISO/IEC 17025 requires laboratories to validate methods and confirm that they are fit for their intended purpose, and suggests a number of procedures that can be used to approach this validation. ISO/IEC 17025 also requires laboratories to establish the traceability of their method back to the International System of Units (SI) or appropriate measurement standards. A laboratory can validate its methods and demonstrate traceability by using appropriate reference materials and/or by the use of calibrated artefacts at critical steps in the process. Traceability can also be demonstrated by other means, eg, standard methods and/or consensus standards. In all these cases the laboratory needs to ensure the mechanism they use to validate their method and to provide the traceability link, is in itself suitably validated and traceable.
- 1.2 UKAS considers the use of reference materials and calibrated artefacts as an important tool for demonstrating the validity and traceability of a method or the component parts of a method.
- 1.3 Reference materials play an important role in underpinning the accuracy and validity of measurements made within testing and calibration laboratories. Purchasers of reference materials require confidence in their accuracy, traceability and homogeneity to be able to determine fitness for purpose. This document will assist laboratories in the selection of appropriate reference materials and provide guidance on determining the competence of reference material suppliers.

2 SCOPE

- 2.1 This document applies to applicant and accredited testing and calibration laboratories. This document is also applicable to inspection bodies that conduct analytical testing or calibration as part of their accredited activities.

3 TERMINOLOGY

- 3.1 *Reference Material (RM)*, material, sufficiently homogenous and stable with respect to one or more of its specified properties, which has been established as fit for its intended use in the measurement process.
- 3.2 *Certified Reference Material (CRM)*, reference material, characterised by a metrologically valid procedure for one or more of its specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and statement of metrological traceability.
- 3.3 *Calibration*, operation establishing the relation between quantity values provided by measurement standards and corresponding indications of a measuring system, carried out under specified conditions and including evaluation of measurement uncertainty.
- 3.4 *Traceability*, 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.

- 3.5 *Homogeneity*, the degree to which a property or constituent is uniformly distributed throughout a quantity of material between separate units of the same material.
- 3.6 *Stability*, the ability of a property value to remain unchanged, within a stated uncertainty, under given storage conditions and a specified timeframe.
- 3.7 *Artefact*, for the purposes of this TPS “artefact” shall be taken to mean, either a single item (e.g. calibration weight) or a material (Solid, Liquid or Gas).
- 3.8 *Property Value*, value attributed to a quantity representing a physical, chemical or biological property of a (certified) reference material.

4 POLICY

- 4.1 It is UKAS policy that all accredited testing and calibration laboratories shall use, where available and appropriate, reference materials or calibrated artefacts for the validation of critical steps and processes in their methodologies.

Note 1: Laboratories should be aware that all stages of the testing/calibration process may need to be validated, and they may need to establish traceability for each stage.

Note 2: Whilst the use of a reference material/standard or calibrated artefact may provide traceability during initial validation, unless it is used routinely within the method it may not provide traceability on an ongoing basis.

- 4.2 Laboratories are required to determine if the artefacts or reference materials used in their methodologies provide a level of traceability that is fit for purpose.

Note 1: UKAS accepts that it may not be feasible to establish traceability for measurements as required by ISO/IEC 17025:2005 5.6 in all cases. However the use of reference materials and/or calibrated equipment/artefacts should be employed by laboratories where available and appropriate to the methodology. Additionally UKAS also acknowledges that:

- a) *The concept of traceability of measurement in fields such as chemical and biological sciences is still partly under international debate and progression towards unified understanding and use of this concept is not yet complete.*
- b) *The role of certified reference materials in providing traceability of measurement results has not yet been fully established internationally.*

- 4.3 Laboratories are required to investigate the availability and suitability of reference materials and calibrated artefacts for their accredited procedures. The competence of organisations conducting the production or calibration of reference materials/artefacts is key to determining the suitability of the materials or artefacts. ISO/IEC 17025 requires laboratories to evaluate suppliers; this includes producers of reference materials and suppliers of calibration services/items. It is important that the laboratory determines the suitability of the producers of these items and not only the distributor.

- 4.4 Upon application for accreditation or extensions to scope, laboratories are required, where reference materials are available but not used for these activities, to submit justification for non-use with the validation data.

Note 1: ISO/IEC Guides 31:2000 and 34:2000 and ILAC G12:2000 contain recommendations and guidance on the requirements for the competence of reference material producers. These documents should be used as a basis for such an evaluation. UKAS accredits reference material producers to ISO Guide 34:2000 in combination with ISO/IEC 17025:2005; a list of accredited producers is available on www.ukas.com. Details of UKAS accredited

calibration laboratories can be found on www.ukas.org. UKAS recommends the use of accredited reference material producers and calibration laboratories where they exist.

Note 2: Whilst no single source of information on the availability of reference materials currently exists, laboratories are recommended to contact reference material producers and distributors to discuss availability and suitability. In addition laboratories may find it useful to refer to the COMAR database for availability of reference materials. COMAR is a non-commercial network of national and international organisations, which is funded by BAM. The website address is www.comar.bam.de.

- 4.5 If no appropriate reference materials or calibrated artefacts are available then the laboratory shall demonstrate that the alternatives used have sufficient traceability, stability, homogeneity and accuracy such that the method and subsequent results can be deemed fit for purpose.
- 4.6 Mandatory use of a specified reference material may be a requirement for some sector schemes or in support of regulatory activities. In these cases UKAS may specify the use of a particular reference material where it is deemed necessary to demonstrate the validity of a method. Where use of a specified reference material is a mandatory requirement, this shall be stated in an appropriate UKAS publication (see UKAS publications list).

5 ADDITIONAL GUIDANCE

- 5.1 There is overlap between ISO/IEC 17025 calibration accreditation and ISO Guide 34 Reference Material Producer accreditation, in that organisations accredited to these standards can both provide materials that can be used as a reference and to provide traceability for analytical methods. Laboratories should consider the following points when selecting the service/product they require.
- 5.1.1 Where the metrological properties of an artefact or instrument have a significant effect on the result of a measurement then calibration is required. This must be performed by a competent laboratory and applies to newly purchased and to existing items. In both cases, defined recalibration criteria are required.

Examples of materials that fall into this category are:

Weights used to calibrate an analytical balance

Thermometers used to monitor the temperature of an incubator

- 5.1.2 Where the laboratory also requires that the artefact is homogenous and stable or if the artefact has the potential for heterogeneity and/or instability, they should purchase an artefact from a reference material producer that can demonstrate that these requirements have been met. Alternatively a competent laboratory could be used to determine homogeneity and stability.

Examples of materials that fall into this category are:

A solution of metals used to calibrate an ICP

Soil with certified dioxin content used for the validation of a dioxin method

Reference cultures for identify and characteristics of microorganisms

Note: A reference material may be used to carry out the purpose of a calibrated artefact, as long as it is suitability accurate and traceable. However, a calibrated artefact can only perform the purpose of a reference material if homogeneity and stability are not relevant or the laboratory determines the homogeneity and stability of the artefact.

6 REFERENCES

6.1 References relating to criteria for the competence of Reference Material Producers.

- 6.1.1 ISO/IEC Guide 31:2000 Guide to the Contents of Certificates and Labels for Reference Materials.
- 6.1.2 ISO/IEC Guide 34:2000 General Requirements for the Competence of Reference Material Producers.
- 6.1.3 ISO/IEC Guide 35:2006 Reference Materials – General and Statistical Principles for Certification.
- 6.1.4 ILAC G12:2000 Guidelines for the Requirements for the Competence of Reference Material Producers.

6.2 References relating to Guidance on the Use and Selection of Reference Materials

- 6.2.1 ISO/IEC Guide 30:1992 Terms and Definitions used in Connection with Reference Materials.
- 6.2.2 ISO/IEC Guide 32:1997 Calibration in Analytical Chemistry and use of Certified Reference Materials.
- 6.2.3 ISO/IEC Guide 33:2000 Uses of Certified Reference Materials.
- 6.2.4 ILAC G9:2005 Guidelines for the Selection and Use of Reference Materials.
- 6.2.5 EA-04/14:2003 The Selection and Use of Reference Materials.
- 6.2.6 Eurachem Guide:2002 The Selection and Use of Reference Materials.

6.3 General References

- 6.3.1 ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.
- 6.3.2 ILAC-P10:2002 ILAC Policy on Traceability of Measurement Results.
- 6.3.3 TPS 41: June 2005 UKAS Policy on Traceability of Measurement.
- 6.3.4 VAM (Valid Analytical Measurement/LGC - Meeting the Traceability Requirements of ISO/IEC 17025: An Analysts Guide (Third Edition).