DAkkS
Deutsche
Akkreditierungsstelle

Technical Note for the Metrological Traceability in the Accreditation Process

71 SD 0 005 | Revision: 1.4 | 01. February 2016

Scope:

This technical note specifies the forms of objective evidence, by which the proof of metrological traceability in the context of the accreditation process is provided by testing and calibration laboratories, medical laboratories, inspection bodies, producers of reference materials and, where applicable, for the accreditation of providers of proficiency testing schemes and bodies operating product certification systems.

Date of the confirmation by the Accreditation Advisory Board: 12.04.2016

The following certificates (hereinafter referred to as reports) are recognized as proof of the metrological traceability for the accreditation of testing and calibration laboratories, medical laboratories, inspection bodies, producers of reference materials, and, where applicable, for the accreditation of providers of proficiency testing schemes and bodies operating product certification systems.

1. Reports by PTB and German designated institutes (DI) within the CIPM MRA.
2. Calibration certificates of German accredited calibration laboratories (with accreditation symbol) in the area covered by the accreditation (DAkkS calibration certificates and DKD calibration certificates).
3. Calibration certificates of foreign calibration laboratories (with accreditation symbol) covered by the accreditation with the accreditation body being signatory to the Multilateral Agreement of EA or ILAC for calibration.
4. Reports of foreign national metrology institutes or designated institutes with a corresponding entry in the CMC lists of BIPM (Appendix C of the CIPM MRA see http://kcdb.bipm.org/appendixC).
5. Reports of certified reference materials with assigned quantity values for which there is a corresponding entry in the CMC lists of BIPM KCDB (e. g. certified reference materials from BAM) and reports of certified reference materials produced by producers of reference materials accredited according ISO Guide 34:2009 (with accreditation symbol).

   Reports of certified reference materials with assigned quantity values for which there is a corresponding entry in the BIPM JCTM lists.

   Reports of certified and non-certified reference materials with assigned quantity values produced by non-accredited reference material producers if it is demonstrated, that they are suitable for the intended use (DIN EN ISO/IEC 17025:2005 Section 4.6.2 or DIN EN ISO 15189:2014 Section 4.6).
6. Reports without accreditation symbol

   All of the following reports shall meet the requirements of DIN EN ISO/IEC 17025:2005, in particular they shall contain a statement about the measurement uncertainty and metrological traceability. The recognition of these reports as proof of metrological traceability is only possible, if the competence of the issuing body for each report is assessed by DAkkS. The result of this assessment is justified and documented in the assessment report.

   Reports without accreditation symbol issued by accredited testing or calibration laboratories shall be as well treated as calibration certificates issued by non-accredited bodies.

6.a) Reports of internal calibrations

This type of metrological traceability is in general possible for all conformity assessment bodies mentioned in the scope of this technical note. For assessments of the competence of the body for the special calibration in accordance with DIN EN ISO/IEC 17025:2005, assessors and technical experts of DAkkS for testing and calibration laboratories, medical laboratories, inspection bodies in their respective scope are used. Technical experts shall only be used when accompanied by an appointed assessor of the accreditation activities K, PL, ML, IS, RM, EP or ZE.

Further information for assessment details are given in the annex.

6.b) Reports without accreditation symbol, issued by non-accredited bodies or by accredited testing or calibration laboratories

This type of metrological traceability is in general possible for all conformity assessment bodies mentioned in the scope of this technical note. For assessments of the competence of the bodies for the special calibration in accordance with DIN EN ISO/IEC 17025:2005 assessors and technical experts of DAkkS for testing and calibration laboratories, medical laboratories, inspection bodies in their respective scope are used. Technical experts shall only be used when accompanied by an appointed assessor of the accreditation activities K, PL, ML, IS, RM, EP or ZE.

Further information for assessment details are given in the annex.

Reports without accreditation symbol, issued by accredited calibration laboratories covered by their accreditation scope are as well not subject to surveillance as part of an accreditation process. Therefore, they shall not be treated as an appropriate evidence of metrological traceability.

7. Where the metrological traceability is technically not possible, the approach for metrological traceability to appropriate standards stated in DIN EN ISO/IEC 17025:2005 section 5.6.2.1.2 shall be applied.

Conformity assessment bodies falling under the scope of this document which have demonstrated metrological traceability through the use of calibration services offered according to section 1 to 4, have made use of services that have been subject to relevant peer review or accreditation. In the situation where section 6 applies, this is not the case; therefore this type of evidence should only be applied when the traceability according to section 1 to 4 is not possible. The conformity assessment bodies falling under the scope of this document must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. DAkkS assesses this evidence and the body's ability to evaluate it using the criteria outlined in the annex.

Annex

To demonstrate the technical competence of the conformity assessment body that perform internal calibrations or issue reports without accreditation symbol, the assessment may include, but is not limited to, the following:

1. Documentation of the validation of self-developed or modified standardized calibration methods (DIN EN ISO/IEC 17025:2005 section 5.4.5) or
   verification using standardized calibration methods (e. g. DIN EN ISO standards, calibration guidelines of EURAMET-, DAkkS-DKD or DKD).
2. Methods for the estimation of measurement uncertainty including the uncertainty budgets (DIN EN ISO/IEC 17025:2005 section 5.4.6).
3. Necessary equipment for special calibration and its suitability to achieve the required accuracy.
   Programme for calibration of equipment and documentation/evidence of metrological traceability (DIN EN ISO/IEC 17025:2005 section 5.6).
4. Documentation/evidence of assuring the quality of calibration results
   (DIN EN ISO/IEC 17025: 2005. section 5.9, for example, inclusion of proficiency tests according to 71 SD 0 010 or comparison with one or more accredited calibration laboratories).
5. Documentation/evidence of the competence of staff by e. g. training certificates for the special calibrations (DIN EN ISO/IEC 17025:2005 section 5.2).
6. Documentation/evidence of the suitability of accommodation and environmental conditions (DIN EN ISO/IEC 17025:2005 section 5.3). Where it is necessary for the special calibration method the environmental conditions shall traceably be recorded.
7. Inclusion of special calibration in internal audits (DIN EN ISO/IEC 17025:2005 section 4.14).
8. On-site visit of the issuing body.

Transitional provisions:

This technical note shall enter into force six months after its publication date mentioned on the front page. Until then the technical note version 1.3 from 25.06.2015 shall be applied.

Classification of DAkkS and DKS calibration certificates

For calibration laboratories accredited by DAkkS, the requirements for calibration certificates are specified in the document DAkkS-DKD-5. There are no further substantial requirements as regards the DAkkS calibration certificates of calibration laboratories as part of quality management audits.

More information can be retrieved from the DAkkS website (www.dakks.de).

List of used abbreviations

BIPM	Bureau International des Poids et Mesures (www.bipm.org/en/about-us/)
CIPM MRA	Mutual recognition Arrangement of national measurements standards and of calibration and measurement certificates issued by national metrology institutes (www.bipm.org/en/cipm-mra/)
CMC	Calibration and Measurement Capabilities
DI	Designated Institutes in Germany: - Bundesanstalt für Materialforschung und –prüfung (BAM); www.bam.de - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL); www.bvl.bund.de - Umweltbundesamt (UBA); www.uba.de
EA	European co-operation for Accreditation (www.european-accreditation.org)
ILAC	International Laboratory Accreditation Cooperation (www.ilac.org)
JCTLM	Joint Committee for Traceability in Laboratory Medicine (www.bipm.org/jctlm)
KCDB	Key Comparison Database (www.kcdb.bipm.org)
MLA	Multilateral Agreement (www.european-accreditation.org/publication/ea-1-06)
PTB	Physikalisch-Technische Bundesanstalt (www.ptb.de)
Akkreditierungsaktivitäten	
PL	Testing laboratories according to DIN EN ISO/IEC 17025:2005
K	Calibration laboratories according to DIN EN ISO/IEC 17025:2005
ML	Medical laboratories according to DIN EN ISO 15189:2014
IS	Inspection bodies according to DIN EN ISO/IEC 17020:2012
RM	Reference material producers according to ISO Guide 34:2009 and DIN EN ISO/IEC 17025:2005
EP	Proficiency test providers according to DIN EN ISO/IEC 17043:2010
ZE	Bodies operating product certification systems according to DIN EN ISO/IEC 17065:2012