



EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE

**MÕÕTMISTE JÄLGITAVUS
PÕHINÕUDED**

***MEASUREMENT TRACEABILITY
GENERAL REQUIREMENTS***

EAK J16 - 2016

Translation from Estonian

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Authorship and principles

This Guidance was prepared by the EAK working group (*including: P. Ruzitš, E. Kulderknup and V. Krutob*) and it replaces the approved version of Guidance EAK J16-2016 of 11.08.2016.

This Guidance is intended to be used by the EAK personnel and assessors/experts, participating in accreditation, accredited laboratories and inspection bodies, and those applying for accreditation.

The principles presented in the Guidance are in compliance with the provisions of guidance documents ILAC-P10 “ILAC Policy on Metrological Traceability of Measurement Results” and ILAC-P14 “ILAC Policy for Measurement Uncertainty in Calibration” and CIPM-ILAC 11.09.05 joint declaration “Improving worldwide traceability and acceptance of measurements carried out within the CIPM MRA and the ILAC Arrangement”

It is not allowed to copy the text of the document for sales purposes.

Official language

If required, the guidance may be translated into other languages. The Estonian version is and must remain like the original.

Further information

In order to get further information on the document please call upon the EAK, Akadeemia tee 21/6, 12618 Tallinn, www.eak.ee.

Confirmation

The Guidance was confirmed by the Member of EAK MB Kristiina Saarniit */digital signature/* on 11.11.2016.

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I GENERAL

1.1 All equipment used for tests and/or calibrations, including equipment for subsidiary measurements, e.g. measurements for environmental conditions, having a significant effect on the accuracy or validity of the result of the test, calibration, inspection or sampling, shall be calibrated before being put into service.

1.2 The property of measurements which enables to link them through an unbroken calibration chain to relevant SI units is called measurement traceability. Measurement traceability is important when results of different measurements must be comparable and when uncertainty of measurement must be determined for certain purposes.

1.3 Traceability shall be assured in the whole measuring range, i.e. the minimum and maximum limits shall be measured traceably with a calibrated measuring instrument. If calibration is performed directly with a reference standard, it shall include a sufficient number of scale division values of the measuring instrument to verify the compliance of the scale with the indications of the reference standard (e.g. linearity or logarithmicity, etc). For the rest of scale division values it is sufficient to prepare a calibration schedule.

1.4 The metrology laboratories (*re: Figure 1*), enabling achievement of measurement traceability in Estonia, are a part of the metrology services of the state as specified in the Metrology Act.

1.5 To assure reliability of the results of measurements the EAK requires its customers to do the following:

- a) all required measurements for the performance of calibrations and tests with compliance, and for which the level of accuracy has a significant effect on the results or validity of calibration, test or inspection, shall be traceable to SI units;
- b) each calibration in the traceability chain shall be performed in compliance with relevant technical requirements (*re: Chapter 3*);
- c) laboratories and inspection bodies shall submit documented evidence (*calibration certificates*) to prove that the above requirements (*a, b*) have been met, that they have had their measuring and test equipment, including reference standards calibrated in an accredited calibration laboratory (*re: Chapter 3*) or they have used certified reference materials;
- d) all the calibration certificates issued by accredited laboratories, bearing the EAK accreditation symbol, shall include a statement on the traceability, uncertainty and probability levels of measurements.

1.6 Calibration and testing laboratories and inspection bodies have set practices of the calibration of their working measuring instruments of work with the help of working standards and reference standards, whereby these standards are also calibrated by applying one or many calibrations with more accurate standards to SI units.

1.7 In some testing areas, e.g. in certain chemical analyses and forensic examination analyses, reference materials are used as reference standards of laboratory. The EAK requires that these reference materials shall be traceable to SI units. Reference materials shall have relevant certificates issued by the competent *producer*.

Note: Reference material producers fulfilling the requirements of ISO 17034 are considered as to be competent.

1.8 Certain calibrations, measurements and analyses cannot be performed in SI units, e.g. in medicine. On such occasions calibration shall assure reliability of measurements by providing traceability to the relevant generally accepted measurement standard.

1.9 This Guidance sets forth general guidelines to laboratories, inspection bodies and assessors for compliance with the EAK traceability requirements. Detailed requirements for compliance with regard to specific measurement and test areas and for compliance are established by the EAK technical committees, if required.

II ASSURING MEASUREMENT TRACEABILITY

2.1 Pursuant to the Metrology Act the assurance of traceability of measurements performed in Estonia is one of the main tasks of the national metrology service. The metrology service includes the Central Office of Metrology, laboratories of national and reference standards, accreditation body (*EAK*), accredited calibration and testing laboratories and verification laboratories. Figure 1 shows the laboratories assuring traceability of measurements in Estonia.

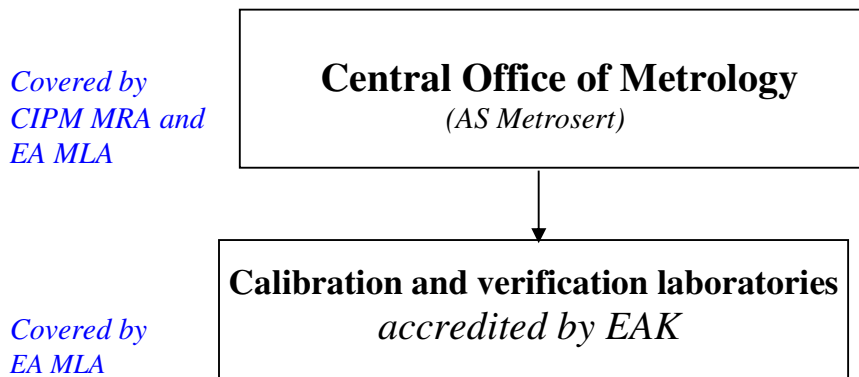


Figure 1. Laboratories assuring attested traceability

2.2 The EAK requires that calibration laboratories assure traceability by having their reference standards calibrated in a laboratory which has the relevant (*Estonian or foreign*) national standard and has joined the CIPM Multilateral Recognition Arrangement, or in a calibration laboratory, capable of performing traceable calibration at required level of uncertainty of measurement and has been accredited by an accreditation body which has joined the ILAC MRA or EA MLA.

2.3 Testing laboratories and inspection bodies shall assure required traceability by having their working measurement instruments calibrated in a calibration laboratory capable of performing traceable calibration at the required level of uncertainty of measurement and that has been accredited by an accreditation body which has joined the ILAC MRA or EA MLA. In case when the provision of calibration service by the aforementioned laboratories is by any reason hindered or not feasible, or it is determined by the required accuracy level, the calibration may be carried out by the relevant national standard laboratory which is joined the ILAC MRA.

Thereby the calibration laboratories must prepare and submit in the calibration certificate or report the scheme of traceability chain which would indicate, as a minimum, identification and the parameters of the used reference standards, uncertainty of measurement and information on persons who calibrated the reference standards.

2.4 In case the traceability of particular calibration can't be established in the way described in clause 2.3, testing laboratories and inspection bodies are permitted to use verification of measuring instruments in case following requirements are fulfilled: the verification laboratory is accredited as an inspection body according to the requirements of ISO/IEC 17020 and all relevant requirements of ISO/IEC 17025 have been assessed according to guidance ILAC-G27; verification certificate or its

appendix includes declaration and sufficient information to prove traceability to SI units and measurement uncertainty of measurement results, presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent). Sufficient information for the interpretation of the measurement uncertainty must be included. In case the calibration report is appended to the verification certificate, the report must fulfil applicable requirements for reporting of results in ISO/IEC 17025.

2.5 When determining the calibration intervals of measuring instruments, the laboratories/bodies must follow the recommendations provided in the document ILAC-G24 and conditions of use of measuring instrument.

2.6 In the period between calibrations laboratories/bodies must determine according to relevant procedures whether the measuring instrument is still working within the limits of defined requirements or not and, if required, present it to unscheduled calibration.

2.7 If software controls or affects the functioning of a measurement instrument, it shall be covered by calibration and measures shall be taken for identification and closing of software to exclude intentional or unintentional changes.

III CALIBRATION

3.1 Performance of calibration

3.1.1 In addition to using the uninterrupted calibration chain for assurance of measurement traceability, it is necessary to perform each calibration in the traceability chain with competence and technically correctly, following calibration methodology and user instructions of the measuring instrument.

3.1.2 Detailed guidelines to calibration laboratories for following the accreditation requirements for assessment of the uncertainty of measurement and presenting the information in calibration certificates is given in the guidance documents EA-4/02 “*Evaluation of the Uncertainty of Measurement in Calibration*” and ILAC-P14 “*ILAC Policy for Measurement Uncertainty in Calibration*”.

3.2 Calibration certificate

3.2.1. Requirements for the content of calibration certificates are provided in EVS-EN ISO/IEC 17025 (cl. 7.8.2, 7.8.4).

3.2.2 Calibration certificates bearing the accreditation symbols of ILAC MRA or EA MLA member bodies assure appropriate traceability.

3.2.3 Calibration laboratories accredited by the EAK shall issue calibration certificates in the scope of their accreditation, bearing exclusively EAK accreditation symbol. It is prohibited to put the EAK accreditation symbol on any certificate issued by the calibration laboratory for the calibration not included in the scope of accreditation. If a calibration laboratory performs calibrations of which some are not in the scope of accreditation of the laboratory, these activities shall be clearly identified on the calibration certificate.

3.2.4 A laboratory/body using calibrated measuring instruments shall prove to the EAK in the course of accreditation that the calibration scope and accuracy, included in their calibration certificate, are appropriate for their needs.

3.3 In-house calibration

3.3.1 Testing and calibration laboratories may calibrate their measuring instruments themselves, provided they can demonstrate their competence and show that when they

perform calibration traceability is assured and they have followed the requirements of EN ISO/IEC 17025:2005 and this document.

3.3.2 Reference standards to be used in in-house calibration shall have been calibrated at the required level of the uncertainty of measurement in a calibration laboratory accredited by an accreditation body which has joined ILAC MRA or EA MLA.

If the reference standard in the laboratory is a reference material, the laboratory shall assure that it was produced, characterised and certified in compliance with requirements.

3.3.3 Results of in-house calibration shall be documented on an appropriate (*re: cl. 3.2.1*) certificate.

3.3.4 In case of in-house calibration appropriateness of measuring standards and reference materials, as well as the capability of the laboratory to calibrate their measuring instruments with them, are verified in the course of accreditation.

IV CASES WHEN ASSURING TRACEABILITY IS COMPLICATED

4.1 It is a generally accepted fact that traceability to SI units is impossible and/or irrelevant in some types of measurements. Measurements of integrated properties of materials, for example, like the definition of textural properties and physico-chemical properties of paper, cloth and yarn and in medical analyses.

However, in case of complicated integrated measurement/analyses with physical properties when comprehensive traceability cannot be realised, it is often possible to differentiate single parameters of measurements or components of equipment for which traceability can be achieved.

4.2 In the event when traceability to SI units cannot be achieved for a measurement which has significant effect on the results of calibration, tests or inspections, laboratories and inspection bodies shall be ready to submit alternative evidence on the traceability of their results.

On such occasions calibration shall assure reliability of measurements achieving traceability to appropriate measurement standards e.g. by the following:

- use of reference materials which give materials reliable physical or chemical characterisation;
- use of special methods and/or agreed reference standards clearly described and agreed by all relevant parties.

If possible, it is necessary to participate in appropriate interlaboratory comparison programmes.

Revisions page

NEW	OLD	Date	Content of amendment	Confirmation
J16-2016	J16-2016	11.11.2016	New revised version of document	<i>/digital signature/</i>
cl. 2.3	cl. 2.3	13.06.2018	Text amended and elaborated	<i>/digital signature/</i>
Autorship and principles (pg 2)	Autorship and principles	26.05.2021	Titles of guides updated	<i>/digital signature/</i>
Further information (pg 2)	Further information	26.05.2021	EAK address updated	<i>/digital signature/</i>
cl. 3.1.2	cl. 3.1.2	26.05.2021	Titles of guides updated	<i>/digital signature/</i>
cl. 3.2.1	cl. 3.2.1	26.05.2021	Ref to clauses of standard updated	<i>/digital signature/</i>
cl. 1.7	cl. 1.7	05.07.2021	Added a note	<i>/digital signature/</i>
cl. 2.4	-	05.07.2021	Added explanation on assurance of traceability via verification	<i>/digital signature/</i>
cl. 2.4	cl. 2.4	27.08.2021	Added clarification on assurance of traceability via verification	<i>/digital signature/</i>