

EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE



PÄDEVUSKATSETE KASUTAMINE
AKREDITEERIMISPROTSESSIS

USE OF PROFICIENCY TESTING
IN THE ACCREDITATION PROCESS

EAK J5 - 2016

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Authorship and principles

This guidance document was prepared by the EAK working group including K. Tõugu, E. Kulderknuup and V. Krutob, and it describes the requirements for laboratories, inspection bodies and measurers with verified competence for participation in proficiency testing and recognition of proficiency testing results in the course of accreditation and assessment processes.

The guidance is based on the principles provided in the EAK Management System Manual (*cl. 5.2.3*) and has taken into account the requirements of standard EVS-EN ISO/IEC 17011 and the guidance document ILAC-P9 “*ILAC policy for participation in proficiency testing activities*”.

This guidance is intended to be used by the EAK personnel and assessors/experts, participating in accreditation and assessment of competence as well as by accredited laboratories and inspection bodies, and those seeking accreditation as well as by measurers with attested competence.

It is not allowed to copy the text of the guidance 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 and shall be binding in case of different opinions concerning interpretation.

Confirmation

The guidance was confirmed by the Member of EAK MB Kristiina Saarniit */digital signature/* on 11.08.2016.

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INTRODUCTION

Proficiency testing and other types of interlaboratory comparison have an important role in the verification of the reliability of results of measurements gained in the course of calibration, testing and inspection and in maintaining the quality of the performance of the laboratory or inspection body. According to the definition provided in the standard EVS-EN ISO/IEC 17043 proficiency testing is the evaluation of participant's performance against pre-established criteria by means of interlaboratory comparisons. The EAK regards proficiency testing and interlaboratory comparisons (*hereinafter interlaboratory comparisons*) and their results as an integral part of the accreditation process of the laboratories and inspection bodies (*hereinafter laboratories*) that perform measurements in the course of inspections.

1 REQUIREMENTS

1.1 Requirements of Estonian legal acts

The obligation of laboratories to participate in comparisons is provided in the following legal acts:

- according to the Metrology Act when interlaboratory comparisons are organized by the Estonian Central Office of Metrology and the EAK, accredited calibration and testing laboratories are obliged to participate in the interlaboratory comparisons related to the methods of testing and measurements included in the accreditation scope of the laboratory;
- according to the Water Act the laboratories performing water research analyses are obliged to participate in annual interlaboratory comparisons organized by reference laboratories, and reference laboratories in turn are obliged to participate in international interlaboratory comparisons;
- according to the Order no 85/2006 of 5.10.2006 of the Minister of Economic Affairs and Communications the measurers with attested competence are obliged to participate in the interlaboratory comparisons involving the methods of testing and measurements within the measurer's scope of competence when interlaboratory comparisons are organized by the EAK.

1.2 International requirements

1.2.1 Requirements of accreditation standards:

- pursuant to EVS-EN ISO/IEC 17025 (*cl. 5.9*) laboratories shall implement quality control procedures for monitoring the validity of tests and calibrations undertaken, which could among other things involve participation in interlaboratory comparisons and proficiency testing programmes;
- pursuant to EVS-EN ISO 15189 (*cl. 5.6.3*) medical laboratories shall participate in relevant interlaboratory comparisons to confirm the reliability of the results of their analyses;
- pursuant to EVS-EN ISO/IEC 17020 (*cl. 6.2.7*) inspection bodies shall maintain evidence for the correlation and accuracy of the inspection results if measurement traceability to the SI units cannot be applied. Application of the above standard ILAC P15 (*cl. 6.2.7c*) explains that one possibility for verification of the correlation and accuracy of inspection results is participation in relevant interlaboratory comparisons and proficiency testing.

1.2.2 Guidance to the laboratories on defining the optimum frequency of participation in interlaboratory comparisons is given in EA-4/18 "*Guidance on the level and frequency of proficiency testing participation*" and ILAC-P9 "*ILAC policy for participation in national and international proficiency testing activities*". The EAK has established their relevant accreditation requirements (*re: cl. 3.1*) based on the above guidance documents.

1.2.3 According to ILAC-P9 requirements laboratories must prepare, follow and regularly revise their interlaboratory comparison plans (*with regard to changes in personnel,*

methodology or equipment). When a laboratory is making a plan, first of all they have to define the specific fields in their activities, e.g. based on different methods of measurement or determining different specific properties, for which the laboratory should participate in interlaboratory comparison at regular intervals. The appropriateness of the plan is assessed in the course of the accreditation process (*r: cl. 3.2*).

1.2.4 Pursuant to the requirements of EVS-EN ISO/IEC 17025 (*cl. 5.9*) laboratories shall thoroughly analyse all the results of interlaboratory comparisons. If the results of interlaboratory comparisons do not meet the objectives established by the laboratory, it will be necessary to apply the nonconforming testing procedure, if required, to define and take corrective action and ensure that the action is effective. Interlaboratory comparisons with unsuccessful results shall be repeated as soon as possible.

2 ORGANIZATION OF INTERLABORATORY COMPARISON AND PARTICIPATION

2.1 The EAK recommendation to accredited laboratories and those seeking accreditation is to participate in interlaboratory comparisons organized in Estonia and/or international interlaboratory comparisons, which are performed according to the provisions of ISO/IEC 17043. Since the number of Estonian laboratories operating in one specific testing/measurement area is limited, only a few interlaboratory comparison schemes (*dominantly with regard to the environmental analyses*) are carried out in Estonia. Therefore EAK recommends laboratories to participate preferably in the IMEP (*IRMM*) and APLAC schemes and those of professional providers of proficiency testing (*re: the EPTIS database*). General information about the most popular internationally recognised interlaboratory comparison programmes is published on the EAK webpage.

2.2 Pursuant to the EA requirements the EAK ensures that the required number of Estonian calibration laboratories (*as a rule at least one*), whose scope of accreditation includes the relevant calibration, will participate in each EA organized intercalibration.

2.3 The EAK coordinates the participation of Estonian accredited laboratories in the interlaboratory comparisons recommended by the relevant working-groups of EA and maintains the relevant database on the participation of Estonian laboratories.

2.4 In Estonia there is a large number of accredited laboratories and/or measurement companies with attested competence in the fields where international interlaboratory comparisons are not organized (*measuring of occupational safety, parameters of electrical installations, roadworthiness tests for vehicles, etc*). To verify their proficiency specific interlaboratory comparisons are organized periodically by proficient Estonian laboratories (*coordinated by the EAK*) and the information is communicated to the interested parties on the EAK webpage and by a relevant circular.

3 INTERLABORATORY COMPARISON AND ACCREDITATION

3.1 Accreditation criteria

According to the accreditation criteria provided in the guidance EAK J1 a laboratory applying for accreditation must verify that they have successfully participated in interlaboratory comparisons for each method of testing/ calibration/inspection in the scope of accreditation they are applying for. The applicant must present relevant documented evidence with the application for accreditation.

Pursuant to the EAK accreditation criteria:

- before accreditation a calibration laboratory must participate in interlaboratory calibrations at least once and after accreditation at least once in five years for each measurand in the scope of accreditation;

- before accreditation a testing laboratory must participate in interlaboratory testing (*if available*) at least once and after accreditation at least once in five years for each group of methodologies based on the same principle of measurement in the scope of accreditation;
- before accreditation a verification laboratory must participate in interlaboratory calibrations or verification at least once and after accreditation at least once in five years for each measurand in the scope of accreditation;
- before accreditation an inspection body (*if applicable*) must participate in interlaboratory comparisons at least once and after accreditation at least once in five years for each group of methodologies based on the same principle of measurement in the scope of accreditation.

3.2 Use of interlaboratory comparison in accreditation

3.2.1 The EAK accreditation process is provided in Guidance EAK J2 in great detail. In the course of the accreditation process the EAK assesses the relevance of the interlaboratory comparison plan of the laboratory and whether it covers the scope of accreditation and the EAK accreditation criteria, and if the laboratory follows the latter. During each on-site assessment of the laboratory the results of interlaboratory comparisons and the analysis of them carried out by the laboratory are assessed (*re: cl. 2.4.2.5 and 5.5.2.2*).

3.2.2 The results of interlaboratory comparison of the laboratory are taken into account when the assessment group prepares recommendations for accreditation. Repeatedly successful performance of the laboratory in interlaboratory comparisons is one of the prerequisites for extension of the supervision interval (*to 18 months*).

3.3 Use of interlaboratory comparison in assessment of measurer's competence

In the course of assessment of the professional competence of a measurer (*re: EAK J23*) the assessors/experts assess the relevance of the measurer's plan to participate in interlaboratory comparisons, following of the plan, analysis of the results of participation in interlaboratory comparison and adequacy of conclusions.

Revisions page

NEW	OLD	Date	Content of amendment	Approval
Autorship and principles pg 2	Autorship and principles pg 2	03.04.2017	Reference to MSM clause elaborated	<i>/digitally signed/</i>
cl. 3.2.1	cl. 3.2.1	03.04.2017	J13 replaced by J2 and reference to clauses of J2 elaborated	<i>/digitally signed/</i>
Autorship and principles	Autorship and principles	25.05.2017	Reference to EA-2/14 cancelled	<i>/digitally signed/</i>
cl. 2.1	cl. 2.1	25.05.2017	Reference to EA-INF/12 cancelled	<i>/digitally signed/</i>
cl. 2.2	cl. 2.2	25.05.2017	Reference to EA-2/14 cancelled	<i>/digitally signed/</i>