EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE

PÄDEVUSKATSETE KASUTAMINE AKREDITEERIMISPROTSESSIS

USE OF PROFICIENCY TESTING IN THE ACCREDITATION PROCESS

EAK J5 – 2016

Translation from Estonian

Tallinn 2016

Authorship and principles

This guidance document was prepared by the EAK working group including K. Tõugu, P. Ružits, T. Tiivel and V. Krutob, and it describes the requirements for laboratories, inspection bodies and measurers with verified competence for participation in proficiency testing and consideration of the 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 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.

Contents

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 enacted in the following legal acts:

a. According to the Metrology Act:
   - the Estonian Central Metrology Authority organizes intercomparison calibrations between the calibration and verification laboratories *[§ 18 cl. 4(5)]*;
   - a National Measurement Standard Laboratory is obliged to participate, in accordance with its competence, in the interlaboratory comparisons organised by the Central Metrology Authority *[(§ 19 cl. 6(9)]*;
   - a Reference Standard Laboratory is required to participate in international intercomparison measurements at the level appropriate to it *[(§ 20 cl. 2(2)].*

b. According to the Water Act:
   - the laboratories performing, in the course of water researches, sampling and physical-chemical or chemical analyses of water, are obliged to participate in annual interlaboratory comparisons in the respective field (*§ 237 cl. 2)*;
   - the reference laboratories are obliged to participate successfully in international interlaboratory comparisons carried out in compliance with the requirements of standard EVS-EN ISO/IEC 17043 *[§ 239 cl. 2(1)]*;
   - a reference laboratory is obliged to organize the interlaboratory comparisons and appraise the results of them *[§ 239 cl. 2(4)].*

c. According to the Regulation No 882/2004/EC (*Article 33*), referred to in the Food Act (*(§ 53),* the National Reference Laboratories, where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing; methods of analysis used thereby can be characterised by the precision of results, values of which can be obtained from a collaborative trial conducted in accordance with an internationally recognised protocol (*e.g. ISO 5725 or IUPAC).*

d. According to the Order no 64 of 13.12.2018 of the Minister of Economic Affairs and Communications the measurers with attested competence are obliged to participate regularly, if applicable, in the appropriate interlaboratory comparisons.

1.2 International requirements and guidelines

1.2.1 Requirements of accreditation standards:

- pursuant to EVS-EN ISO/IEC 17025 (*cl. 7.7.2*) laboratories shall monitor their performance by comparison with results of other laboratories, where available and appropriate, participating in proficiency testing or interlaboratory comparisons other than proficiency testing;

- pursuant to EVS-EN ISO 15189 (*cl. 5.6.3*) medical laboratories shall participate in the interlaboratory comparison programme(s) appropriate to the examination and interpretations of examination results;
- pursuant to EVS-EN ISO/IEC 17020 (*cl. 6.2.7*) inspection bodies shall maintain evidence of correlation or accuracy of inspection results, where measurement traceability to the SI units cannot be applied. According to ILAC P15 (*cl. 6.2.7c*) one possibility for verification of the correlation and accuracy of inspection results is participation in the 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 these guidance documents.

1.2.3 According to ILAC-P9 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. 7.7.3*) 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 appropriate action to prevent incorrect results from being reported.

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 either in Estonia or internationally, which are performed according to the provisions of EVS-EN 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, the EAK recommend 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 (*www.eak.ee/uudised/võrdluskatsed*).

2.2 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, etc.*). To verify their proficiency specific interlaboratory comparisons are organized periodically by proficient Estonian laboratories, whereas the relevant information is communicated to the interested parties by the relevant circulars.

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 submit 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 outlined in guidance EAK J2 in great detail. In the course of the accreditation process the EAK assess 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.

3.2.2 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 6.5.2.2*). Guidelines on assessment whether the interlaboratory comparisons, that have been organized among only a few (2-7) laboratories, were appropriate and the results of them can be appraised and considered in the laboratory accreditation process, are given in the guidance EA-4/21 INF.

3.2.3 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 the 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	*/digitally signed/*
cl. 3.2.1	cl. 3.2.1	03.04.2017	J13 replaced by J2 and reference to clauses of J2 elaborated	*/digitally signed/*
Autorship and principles	**Autorship and principles**	25.05.2017	Reference to EA-2/14 omitted	*/digitally signed/*
cl. 2.1	cl. 2.1	25.05.2017	Reference to EA-INF/12 omitted	*/digitally signed/*
cl. 2.2	cl. 2.2	25.05.2017	Reference to EA-2/14 omitted	*/digitally signed/*
cl. 1.1	cl. 1.1	09.12.2019	Provisions of legal acts updated	*/digitally signed/*
cl. 1.2.1	cl. 1.2.1	09.12.2019	Requirements of standards elaborated	*/digitally signed/*
Ch. 2	Ch. 2	09.12.2019	Information on organization of ILCs updated	*/digitally signed/*
cl. 3.2.2	cl. 3.2.2	09.12.2019	Added ref to EA guidance	*/digitally signed/*