



EESTI AKREDITEERIMISKESKUS  
ESTONIAN ACCREDITATION CENTRE

# **EAK ACCREDITATION CRITERIA**

## ***EAK AKREDITEERIMISKRITEERIUMID***

### **EAK J1 – 2015**

Translation from Estonian

Tallinn 2015

### *Autorship and basic principles*

This guidance document has been produced by an EAK task force (*composition: Kristiina Saarniit, Eire Endrekson, Paavo Ruzišt and Viktor Krutob*) and it replaces the document “EAK accreditation requirements” confirmed on 30.12.2014.

The guidance presents accreditation criteria for various types of conformity assessment activities for which EAK is competent to perform accreditation.

Observance of the criteria set in this guidance is mandatory for conformity assessment bodies applying for or holding valid accreditation.

### *Official language*

Text of this document may be translated into other languages as required. The Estonian language version remains the definitive one.

### *Confirmation*

This document was confirmed by Kristiina Saarniit, Director of EAK, on 15.09.2015.

## Contents

<u>Chapter</u>	<u>Page</u>
<b>I INTRODUCTION</b>	4
<b>II EAK ACCREDITATION CRITERIA</b>	5
1. LABORATORIES	5
2. PROFICIENCY TESTING PROVIDERS	6
3. INSPECTION BODIES	7
4. BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES	8
5. BODIES CERTIFYING PERSONS	9
6. MANAGEMENT SYSTEMS (MS) CERTIFICATION BODIES	10
7. GREENHOUSE GAS VERIFIERS	12
8. ENVIRONMENTAL VERIFIERS	13
9. CAB SEEKING NOTIFICATION	14
<b>Revisions page</b>	15

## I INTRODUCTION

This guidance document presents the accreditation criteria established by the Estonian Accreditation Centre (*hereinafter EAK*) for various types of conformity assessment bodies (*hereinafter CAB*), which shall be complied with by any CAB applying for or holding accreditation.

Accreditation criteria are established pursuant to the requirements of Regulation (EC) No 765/2008 (*Article 8 cl. 5*) and standard EVS-EN ISO/IEC 17011 (*cl. 7.1, 8.2.1*) prescribing that a national accreditation body shall identify the conformity assessment activities for which it is competent to perform accreditation and establish general criteria for accreditation, based on the relevant legal acts and normative documents (*i.e. international standards and guidance documents*). Besides the accreditation body shall set specific technical requirements for different fields of conformity assessment, where applicable.

Compliance of CABs with the criteria set in this guidance is assessed by EAK in the course of accreditation and surveillance assessments.

In the accreditation criteria references are made to the following international organisations on accreditation: **EA** – European cooperation for Accreditation, **ILAC** – International Laboratory Accreditation Cooperation, **IAF** – International Accreditation Forum.

Forms for application and EAK guidance documents referred to hereafter are available from the EAK webpage at address [www.eak.ee](http://www.eak.ee), EA documents from [www.european-accreditation.org](http://www.european-accreditation.org), ILAC documents from [www.ilac.org](http://www.ilac.org) and IAF documents from [www.iaf.nu](http://www.iaf.nu).

## II EAK ACCREDITATION CRITERIA

### 1. LABORATORIES

1.1 General accreditation requirements for laboratories are set out in the standard EVS-EN ISO/IEC 17025:2017\* “General requirements for the competence of testing and calibration laboratories”.

1.2 General accreditation requirements for medical laboratories are set out in the standard EVS-EN ISO 15189:2012 „Medical laboratories. Requirements for quality and competence“.

1.3 To comply with the accreditation requirements laboratories shall also follow requirements of the following guidance documents:

- ILAC P10 „ILAC Policy on Traceability of Measurement Results“ and EAK J16 “Traceability of measurements. General requirements”;
- ILAC P9 „ILAC Policy for Participation in Proficiency Testing Activities“ and EAK J5 „Use of proficiency testing in the accreditation process“;
- EA-2/15 „EA Requirements for the Accreditation of Flexible Scopes“ and EAK J19 „Flexible scope of accreditation. General principles and conduct of assessment“ (*if applicable*).

1.4 Where making reference to accreditation laboratories shall follow the guidance document EAK J9 „Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status“.

1.5 Calibration laboratory shall also comply with the following requirements:

- to estimate and express the measurement uncertainty according to the guidance documents EA-4/02 “Expressions of the Uncertainty of Measurements in Calibration” and ILAC P14 „ILAC Policy for Uncertainty in Calibration“;
- to participate in intercalibration at least once before accreditation and at least once per 5 years after accreditation by each measurand belonging to its scope of accreditation.

1.6 Testing laboratory shall also comply with the following requirements:

- to participate in interlaboratory comparison or proficiency tests at least once before accreditation and at least once per 5 years after accreditation by each group of procedures within its scope of accreditation based on the same measurement principle.

1.7 Measuring instruments` verification laboratory shall also participate in intercalibration or – verification at least once before accreditation and at least once in 5 years after accreditation by each measurand belonging to its scope of accreditation.

1.8 Medical laboratory shall also comply with the requirements of the document EA-4/17 „EA Position Paper on the description of scopes of accreditation of medical laboratories“.

1.9 Accreditation of laboratories will be carried out according to the guidance document EAK J2 „Procedure for accreditation assessment“ taking into account, if applicable, the guidelines given in the documents EAK VJ3 „Instruction on description and witnessing of accreditation scopes of calibration laboratories“, EAK VJ5 „Instruction on assessment and description of accreditation scopes of testing laboratories“, EAK VJ6 „Instruction on assessment and description of accreditation scopes of medical laboratories“ and EAK VJ8 „Instruction on assessment and description of accreditation scopes of the measuring instruments` verification laboratories and conformity assessment bodies“.

## **2. PROFICIENCY TESTING PROVIDERS**

2.1 General accreditation requirements for the proficiency testing (PT) providers are set out in the standard EVS-EN ISO/IEC 17043:2010 “Conformity assessment. General requirements for proficiency testing“.

2.2 To comply with the accreditation requirements the PT providers shall also follow the guidance documents ILAC P10 „ILAC Policy on Traceability of Measurement Results“ and EAK J16 “Traceability of measurements. General requirements”, if applicable.

2.3 Where making reference to accreditation a PT provider shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status“.

2.4 Accreditation of PT providers will be carried out according to the guidance documents EAK J2 „Procedure for accreditation assessment“ and EAK J20 “The conduct of assessment of a PT provider“.

### 3. INSPECTION BODIES

3.1 General accreditation requirements for the inspection bodies are set out in the standard EVS-EN ISO/IEC 17020:2012 „Conformity assessment. Requirements for the operation of various types of bodies performing inspection“.

3.2 To comply with the accreditation requirements an inspection body shall also follow the requirements of the document ILAC P15:2016 “Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies“ (*NB! Application date for ILAC P15:2020 – Nov. 2021*).

3.3 To ensure traceability and reliability of measurements carried out in the course of inspection, an inspection body shall:

- follow the guidance documents ILAC P10 „ILAC Policy on Traceability of Measurement Results“ and EAK J16 “Traceability of measurements. General requirements”;
- follow the guidance documents ILAC P9 „ILAC Policy for Participation in Proficiency Testing Activities“ and EAK J5 „Use of proficiency testing in the accreditation process“;
- participate in interlaboratory comparison or proficiency tests at least once before accreditation and at least once per 5 years after accreditation by each group of procedures based on the same measurement principle.

3.4 Where making reference to accreditation an inspection body shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status".

3.5 Accreditation of inspection bodies will be carried out according to the guidance document EAK J2 „Procedure for accreditation assessment“ taking into account the guidelines given in the document EAK VJ9 „Instruction on description of accreditation scopes and planning of assessment of inspection bodies“ and, if applicable, EAK VJ7 „Instruction on assessment and description of accreditation scopes of electrical installations` inspection bodies“.

#### **4. BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES**

4.1 General accreditation requirements for the bodies certifying products, processes and services are set out in the standard EVS-EN ISO/IEC 17065:2012 „Conformity assessment. Requirements for bodies certifying products, processes and services“.

4.2 Bodies operating certification of welding activities shall also comply with the requirements of the guidance document EA-6/02 “EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834”.

4.3 Bodies operating certification of the PEFC chain of custody shall also comply with the requirements of the PEFC international standard ST 2003:2012 (*second edition 17.11.2014*) and ST 2003:2020 (transition period till 14.08.2022).

4.4 Where making reference to accreditation a certification body shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status".

4.5 Accreditation of the bodies certifying products, processes and services will be carried out according to the guidance document EAK J2 „Procedure for accreditation assessment“ taking into account the guidelines given in the document EAK VJ4 „Specific instruction on assessment of products/processes/services certification activities“.



## **5. BODIES CERTIFYING PERSONS**

5.1 General accreditation requirements for the bodies operating certification of persons are set out in the standard EVS-EN ISO/IEC 17024:2012 „Conformity assessment. General requirements for bodies operating certification of persons“.

5.2 Where making reference to accreditation a certification body shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status".

5.3 Accreditation of the persons` certification bodies will be carried out according to the guidance document EAK J2 „Procedure for accreditation assessment“ taking into account the guidelines given in the document EAK VJ1 „Instruction on description of accreditation scopes and planning of assessment of persons` certification bodies“.

## 6. MANAGEMENT SYSTEMS (MS) CERTIFICATION BODIES

6.1 General accreditation requirements for the MS certification bodies are set out in the standard EVS-EN ISO/IEC 17021-1:2015 „Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements“.

6.2 To comply with the accreditation criteria a MS certification body shall also follow the requirements of the following documents:

- IAF MD 1 „IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization“;
- IAF MD 2 „IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems“;
- IAF MD 4 „IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment purposes“;
- IAF MD 10 “IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011”;
- IAF MD 11 „Application of ISO/IEC 17021 for Audits of Integrated Management Systems“

6.3 Where making reference to accreditation a MS certification body shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status".

6.4 Quality MS (QMS) certification bodies shall also follow the requirements of the following documents:

- ISO/IEC 17021-3:2017 „Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 3: Competence requirements for auditing and certification of quality management systems“;
- IAF MD 5 „ Determination of Audit Time of Quality, Environmental and Occupational Health & Safety Management Systems“.

6.5 Environmental MS (EMS) certification bodies shall also follow the requirements of the following documents:

- ISO/IEC 17021-2:2016 „Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 2: Competence requirements for auditing and certification of environmental management systems“;
- IAF MD 5 „ Determination of Audit Time of Quality, Environmental and Occupational Health & Safety Management Systems“;
- EA-7/04 „Legal Compliance as a part of accredited ISO 14001:2015 certification“.

6.6 Occupational health and safety MS (OH&SMS) certification bodies shall also follow the requirements of the following documents:

- ISO/IEC TS 17021-10:2018 „Conformity assessment – Requirements for bodies providing audit and certification of management systems -- Part 10: Competence requirements for auditing and certification of occupational health and safety management systems“;
- IAF MD 22 „Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)“;
- IAF MD 5 “Determination of Audit Time of Quality, Environmental and Occupational Health & Safety Management Systems”.

6.7 Food safety MS (FSMS) certification bodies shall also comply with the requirements of the technical specification ISO/TS 22003:2013 „Food safety management systems. Requirements for bodies providing audit and certification of food safety management systems“.

6.8 Bodies operating certification of QMS of welding activities shall also comply with the requirements of guide EA-6/02 "EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834".

6.9 PEFC forest management certification bodies shall also comply with the requirements of the following documents:

- „PEFC Certification and Accreditation Procedures“ Annex 6;
- PEFC forest management national standards setting additional requirements for the certification bodies (*PEFC EST 2, PEFC EST 3, PEFC EST 4, PEFC DK 005-3*).

6.10 Accreditation of the MS certification bodies will be carried out according to the guidance document EAK J2 „Procedure for accreditation assessment“, taking into account the guidelines given in the documents EAK VJ2 „Specific instruction on assessment of management systems` certification activities“, IAF MD 15 „IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies` Performance“, IAF MD 16 „Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies“ and IAF MD 17 “Witnessing Activities for the Accreditation of Management Systems Certification Bodies“.

## **7. GREENHOUSE GAS VERIFIERS**

7.1 General accreditation requirements for the greenhouse gas (GHG) verifiers are set out in the standard EVS-EN ISO 14065:2013 „Greenhouse gases. Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition“, and in the Commission Regulation (EU) No 2018/2067 on the verification of greenhouse gas emission reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council and Commission Regulation (EU) No 2019/1842 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes.

7.2 To conform to the accreditation criteria the GHG verifiers shall also follow the requirements of the standard EVS-EN ISO 14064-3:2012 “Greenhouse gases. Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions” as well as the following guidance documents:

- EA-6/03 “EA Document for Recognition of Verifiers under the EU ETS Directive”;
- IAF MD 6 “Application of ISO 14065:2013”.

7.3 Where making reference to accreditation the GHG verifiers shall follow the requirements of the guidance document EAK J9 “Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status”.

7.4 Accreditation of the GHG verifiers will be carried out according to the guidance documents EAK J2 „Procedure for accreditation assessment“, EAK J21 „The conduct of assessment of a GHG verifier“ and IAF MD 14 “Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)”.

## **8. ENVIRONMENTAL VERIFIERS**

8.1 General accreditation requirements for the environmental verifiers are set out in the Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisation in a Community eco-management and audit scheme (EMAS)<sup>1</sup> [*changed by the Commission`s Regulations (EU) of 28.08.2017 No 2017/1505 and of 19.12.2018 No 2018/2026*].

8.2 The EMAS environmental verifiers shall also follow the applicable requirements of the standard EVS-EN ISO/IEC 17021-1:2015 „Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements“.

8.3 Where making reference to accreditation the EMAS environmental verifiers shall follow the requirements of the guidance document EAK J9 "Conditions for the use of EAK logo, accreditation symbol and reference to accreditation and MLA Signatory status“.

8.4 Where notifying the local accreditation body about its verification activity in a Member State other than that where the accreditation was granted, the EMAS environmental verifier shall follow the requirements set forth in the Commission Decision No 2016/1621/EU.

8.5 Accreditation of EMAS verifiers will be carried out according to the guidance documents EAK J2 „Procedure for accreditation assessment“ and EAK J18 „The guide for assessment of an EMAS environmental verifier“.

---

<sup>1</sup> The relevant European documents are available from the address [europa.eu.int/comm/environment/emas/documents](http://europa.eu.int/comm/environment/emas/documents).

## **9. CAB SEEKING NOTIFICATION**

9.1 When accrediting a CAB seeking notification apart from the accreditation criteria also the requirements listed in the guidance document EA-2/17 “EA Document on Accreditation for Notification Purposes” are taken into account.

9.2 The CABs seeking notification will be accredited against the requirements of the standards referred to in the relevant Estonian legislation and/or guidance document EA-2/17 (*re: tables 2 and 3*) as preferred ones for the particular modules and directives/regulations.

## Revisions page

NEW	OLD	Date	Essence of change	Confirmation
clause (cl.) 1.5	cl. 1.5	18.01.2016	“4” replaced by “5”	/digitally signed/
cl. 1.6	cl. 1.6	18.01.2016	Text elaborated	/digitally signed/
cl. 1.7	cl. 1.7	18.01.2016	“2,5” replaced by “5”	/digitally signed/
cl. 3.3	cl. 3.3	18.01.2016	Text elaborated	/digitally signed/
cl. 1.3, 3.3	cl.1.3, 3.3	03.04.2017	Added reference to ILAC P9 and EAK J5	/digitally signed/
cl. 1.4, 2.3, 3.4, 4.3, 5.2, 6.3, 7.3, 8.3	cl. 1.4, 2.3, 3.4, 4.3, 5.2, 6.3, 7.3, 8.3	03.04.2017	Name of J9 changed	/digitally signed/
cl. 1.9	cl. 1.9	03.04.2017	J13 replaced by J2	/digitally signed/
cl. 2.2	cl. 2.2	03.04.2017	Added ref to ILAC P10	/digitally signed/
cl. 2.4, 7.4, 8.4	cl. 2.4, 7.4, 8.4	03.04.2017	Added ref to EAK J2	/digitally signed/
cl. 3.5, 4.4, 5.3, 6.9	cl. 3.5, 4.4, 5.3, 6.9	03.04.2017	J17 replaced by J2	/digitally signed/
cl. 6.2	cl. 6.2	03.04.2017	Added ref to IAF MD 19	/digitally signed/
cl. 3.5	cl. 3.5	08.05.2017	Added ref to VJ17-2	/digitally signed/
cl. 4.3	-	08.05.2017	Added ref to PEFC standard	/digitally signed/
cl. 6.1	cl. 6.1	08.05.2017	Added ref to ISO 17021-1 and transition date	/digitally signed/
cl. 6.2	cl. 6.2	08.05.2017	Added ref to IAF MD 10	/digitally signed/
cl. 6.5	cl. 6.5	08.05.2017	Added ref to ISO 17021-2:2016 and transition date	/digitally signed/
cl. 6.6	-	08.05.2017	Added ref to EA-3/13	/digitally signed/
cl. 6.9	cl. 6.8	08.05.2017	Added PEFC EST standards	/digitally signed/
cl. 6.10	cl. 6.9	08.05.2017	Added ref to VJ17-1 and 3 IAF MD	/digitally signed/
cl. 7.4	cl. 7.4	08.05.2017	Added ref to IAF MD 14	/digitally signed/
cl. 8.2	cl. 8.2	08.05.2017	Added ref to ISO 17021-1 and transition date	/digitally signed/
cl. 9	-	08.05.2017	Added specific requirements for CABs seeking notification	/digitally signed/
cl. 8.4	-	30.08.2017	Added ref to EU Commission Decision	/digitally signed/
cl. 8.5	cl. 8.4	30.08.2017	New number of a clause	/digitally signed/
cl. 1.9	cl. 1.9	13.12.2017	Added ref to EAK VJ3 and VJ5	/digitally signed/
cl. 4.5	cl. 4.5	13.12.2017	Added ref to EAK VJ4	/digitally signed/
cl. 6.2	cl. 6.2	13.12.2017	Added application dates for IAF MD 2 and MD 19	/digitally signed/
cl. 6.4	cl. 6.4	13.12.2017	Ref to standard updated	/digitally signed/
cl. 6.5	cl. 6.5	13.12.2017	Ref to standard updated	/digitally signed/
cl. 6.9	cl. 6.9	13.12.2017	Added Danish PEFC standard	/digitally signed/
cl. 6.10	cl. 6.10	13.12.2017	Added ref to EAK VJ2	/digitally signed/
cl. 9.2	-	13.12.2017	Added ref to preferred standards	/digitally signed/

<b>NEW</b>	<b>OLD</b>	<b>Date</b>	<b>Essence of change</b>	<b>Confirmation</b>
cl. 1.9	cl. 1.9	20.03.2018	Added ref to EAK VJ5 ( <i>revised version</i> ), VJ6 and VJ8 ( <i>replacing EAK J15</i> )	<i>/digitally signed/</i>
cl. 3.5	cl. 3.5	20.03.2018	Added ref to EAK VJ7 ( <i>replacing EAK VJ17-2</i> ) and VJ9	<i>/digitally signed/</i>
cl. 5.3	cl. 5.3	20.03.2018	Added ref to EAK VJ1	<i>/digitally signed/</i>
cl. 6.2	cl. 6.2	20.03.2018	Name of IAF MD 1 changed, IAF MD 19 omitted	<i>/digitally signed/</i>
cl. 6.4, 6.5	cl. 6.4, 6.5	20.03.2018	Name of IAF MD 5 changed	<i>/digitally signed/</i>
cl. 6.6	cl. 6.6	20.03.2018	Added ref to IAF MD 22	<i>/digitally signed/</i>
Introduction	Introduction	20.06.2018	Ref to ISO 17011 updated	<i>/digitally signed/</i>
cl. 1.1	cl. 1.2	20.06.2018	Ref to ISO 17025 updated and amended by transition period	<i>/digitally signed/</i>
cl. 6.6	cl. 6.6	20.06.2018	Ref to EA document omitted	<i>/digitally signed/</i>
cl. 8.1	cl. 8.1	20.06.2018	Added ref to Regulation	<i>/digitally signed/</i>
cl. 6.2	cl. 6.2	23.01.2019	Added transition period to IAF MD 4	<i>/digitally signed/</i>
cl. 6.6	cl. 6.6	23.01.2019	References updated	<i>/digitally signed/</i>
cl. 6.2	cl. 6.2	17.04.2019	Added transition period to IAF MD 11	<i>/digitally signed/</i>
cl. 8.1	cl. 8.1	17.04.2019	Added ref to Regulation	<i>/digitally signed/</i>
cl. 6.4, 6.5, 6.6	cl. 6.4, 6.5, 6.6	04.06.2019	Added transition period to IAF MD5:2019	<i>/digitally signed/</i>
cl. 6.6	cl. 6.6	04.06.2019	Added transition period to IAF MD 22:2019	<i>/digitally signed/</i>
cl. 7.1	cl. 7.1	04.06.2019	Added ref to new Regulation	<i>/digitally signed/</i>
cl. 6.2	cl. 6.2	29.10.2019	Elaborated transition period	<i>/digitally signed/</i>
cl. 3.2	cl. 3.2	08.09.2020	Added the new version of ILAC P15	<i>/digitally signed/</i>
cl. 6.2, 6.4, 6.5, 6.6	cl. 6.2, 6.4, 6.5, 6.6	08.09.2020	Title of IAF MD5 elaborated and transition periods updated	<i>/digitally signed/</i>
cl. 7.1	cl. 7.1	08.09.2020	Added legal act	<i>/digitally signed/</i>
cl. 4.3	cl. 4.3	13.04.2021	Added new version of PEFC standard and transition date	<i>/digitally signed/</i>
cl. 1.6	cl. 1.6	26.05.2021	Deleted reference to old guide	<i>/digitally signed/</i>