SLOVENSKA AKREDITACIJA

D05-10

POLICY, GUIDANCE AND INTERPRETATION DOCUMENTS

Table of Contents

1 PURPOSE 2

2 GENERAL 2

3 LIST OF DOCUMENTS BY FIELDS OF ACCREDITATION 2

3.1 All types of bodies 2

3.2 Laboratories 2

3.3 Inspection bodies 3

3.4 Certification bodies 3

3.5 Environmental verifiers 5

3.6 Verifiers of greenhouse gas emission reports 5

4 CHANGES SINCE THE PREVIOUS REVISION 6

5 TRANSITORY AND FINAL PROVISIONS 6

6 CONTROL OF THE DOCUMENT 6

1 PURPOSE

This document is intended for clients and accreditation procedure operators to inform them about the policy, guidance and interpretation documents concerning the requirements applied by SA when assessing the competence of conformity assessment bodies.

2 GENERAL

The requirements for the competence of conformity assessment bodies are laid down in Rules of Accreditation (S03).

This document covers documents of ILAC, IAF, EA, EURACHEM, EUROLAB and EU as well as the OA documents adopted by the SA Accreditation Committee. The OA documents are accessible on SA's website, while those of the international organisations and associations are accessible on the issuers' websites.

The next section lists the documents that shall be used for different types of conformity assessment activity and for different technical fields. In addition, also other guidance and interpretation documents specific to particular fields of work of the respective accredited bodies (e.g., documents of professional organisations and associations) shall be used in assessments. When, within the scope of conformity assessment procedures, an accredited body performs other types of conformity assessment, the relevant guidance for that other type of conformity assessment shall also be used (e.g. guidance for testing and calibration laboratories shall be used in accreditation procedures for inspection and certification bodies, when the inspection/certification body performs testing or calibration as basis for decision making on inspection/certification).

3 LIST OF DOCUMENTS BY FIELDS OF ACCREDITATION

3.1 All types of bodies

SA uses the following documents in assessing all conformity assessment bodies:

- ***OA02*** *(Rev. 8): Acceptable metrological traceability of measurement results*,
- ***OA08 (****Rev. 4): Accredited CAB reporting*.

3.2 Laboratories

The following documents shall be used in assessing all laboratories:

- ***OA12*** *(Rev. 1): Equipment control*,
- ***OA05*** *(Rev. 5): Participation in interlaboratory comparisons*,
- ***ILAC G24*** *(2022): Guidelines for the determination of recalibration intervals of measuring equipment*,

while the documents stated under points 3.2.1, 3.2.2 and 3.2.3 shall only be used in the respective areas.

3.2.1 Calibration laboratories

- ***EA-4/02 M*** *(Rev.03, Apr 2022): Evaluation of the uncertainty of measurement in calibration,*
- ***ILAC G8*** *(09/2019): Guidelines on decision rules and statements of conformity*,

- ***ILAC P14*** *(09/2020): Policy for measurement uncertainty in calibration*,
- ***EUROLAB Guidance for the management of computers and software in laboratories with reference to ISO/IEC 17025/2005*** *(okt 2006)*.

3.2.2 Testing laboratories

- ***OA10*** *(Rev. 2): ILAC Guidelines for measurement uncertainty in testing (ILAC-G17:01/2021)*,
- ***ILAC G8*** *(09/2019): Guidelines on decision rules and statements of conformity*,
- ***EUROLAB Guidance for the management of computers and software in laboratories with reference to ISO/IEC 17025/2005*** *(okt 2006)*.

Depending on the area of activity in the accreditation procedures for testing laboratories the following guidance and interpretation documents can also be used:

- ***OA03*** *(Rev. 5): Uncertainty of measurement in sampling and chemical testing*,
- ***OA04*** *(Rev. 3): Measurements of wastewater flows*,
- ***OA06*** *(Rev. 2): Translation of EA-4/14 Selection and use of reference materials*,
- ***OA15*** *(Rev. 2): Environmental noise reporting guidance*,
- ***EA-4/09 G*** *(Rev03, Jun 2022): Accreditation for sensory testing laboratories*,
- ***EA-4/22 G*** *(rev00, Nov 2018): Guidance on accreditation of pesticide residues analysis in food and feed*,
- ***ILAC G19*** *(06/2022): Modules in a forensic science process*,
- ***Eurachem/CITAC Guide: Guide to quality in analytical chemistry*** *(3rd ed., 2016)*,
- ***Eurachem Guide: Accreditation for microbiological laboratories*** *(3rd ed., 2023)*,
- ***European technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs*** *(2nd ver., 2014), JRC Scientific and policy reports – Guidance ISO/IEC 17025*.

3.2.3 Medical laboratories

- ***OA06*** *(Rev. 2): Translation of EA-4/14 Selection and use of reference materials*.

3.3 Inspection bodies

- ***OA07d3*** *(Rev. 1): Scope of accreditation in inspection*,
- ***OA12*** *(Rev. 1): Control of equipment*,
- ***OA14*** *(Rev. 3): Application of ISO/IEC 17020:2012 for the accreditation of inspection bodies*,
- ***ILAC G27*** *(07/2019): Guidance on measurements performed as part of an inspection process.*

In accreditation procedures for inspection bodies for notification purposes to *Directive 2014/31/EU* (NAWI) for modules F, F1 and for notification purposes to *Directive 2014/32/EU* (MID) for modules F, F1, the guidance document ***WELMEC Guide 8.7*** *(Version 2021)* shall also apply.

3.4 Certification bodies

3.4.1 Certification bodies for products, processes and services

Depending on the area of activity in the accreditation procedures for certification bodies that certify products/processes/services, the following guidance and interpretation documents shall also be used:

- ***EA-6/02 M*** *(Rev03, Jan 2022): Guidelines on the use of ISO/IEC 17065 and ISO/IEC 17021-1 for certification to EN ISO 3834*,
- ***IAF MD 4*** *(Jun 2023): Use of Information and Communication Technology (ICT) for auditing / assessment purposes*,
- (EU and third countries) ***Other applicable documentation published by the European Commission regarding Regulation (EU) 2018/848***,
- (third countries) ***Commission delegated Regulation (EU) 2021/1697*** *of 13 July 2021 amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the criteria for the recognition of control authorities and control bodies that are competent to carry out controls on organic products in third countries, and for the withdrawal of their recognition*,
- (third countries) ***Commission delegated Regulation (EU) 2021/1342*** *of 27 May 2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the information to be sent by third countries and by control authorities and control bodies for the purpose of supervision of their recognition under Article 33(2) and (3) of Council Regulation (EC) No 834/2007 for imported organic products and the measures to be taken in the exercise of that supervision* with amendments accessible on: *https://eur-lex.europa.eu/eli/reg_del/2021/1342*, consolidated text,
- (third countries) ***Codex Alimentarius Commission Guideline GL 32-1999*** *(2013): Guidelines for the production, processing, labelling and marketing of organically produced foods* (*http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/*).

In accreditation procedures for certification bodies certifying products/processes/services for notification purposes to *Directive 2014/31/EU* (NAWI) for modules B, D, D1, G and for notification purposes to *Directive 2014/32/EU* (MID) for modules B, D, D1, G, the guidance document ***WELMEC Guide 8.5*** *(Version 2022)* shall also apply

3.4.2 Certification bodies for management systems

Depending on the area of application in the accreditation procedures for certification bodies that certify management systems, the following guidance and interpretation documents can also be used:

SCHEME / DOCUMENTS	ISO 9001	ISO 14001	ISO 13485	ISO 22000	ISO 45001	ISO 50001	End-of-waste criteria	EN 15224
IAF MD 1 *(Oct 2023): Audit and certification of a management system operated by a multi-site organization*	✓	✓	✓	✓*2	✓	✓*2	✓	✓
IAF MD 2 *(Jun 2023): Transfer of accredited certification of management systems*	✓	✓	✓	✓	✓	✓	✓	✓
IAF MD 4 *(Jun 2023): Use of Information and Communication Technology (ICT) for auditing / assessment purposes*	✓	✓	✓	✓	✓	✓	✓	✓
IAF MD 5 *(Jun 2023): Determination of audit time of quality, environmental, and Occupational Health & Safety management systems*	✓	✓	✓*1	✓*1	✓	✓*1	✓	✓
IAF MD 9 *(Nov 2023): Application of ISO/IEC 17021-1 in the field of medical device quality management systems (ISO 13485)*			✓					

DOCUMENTS \ SCHEME	ISO 9001	ISO 14001	ISO 13485	ISO 22000	ISO 45001	ISO 50001	End-of-waste criteria	EN 15224
IAF MD 11 *(Sep 2023): Application of ISO/IEC 17021 for audits of integrated management systems*	✓	✓	✓	✓	✓	✓	✓	✓
IAF MD 22 *(Jun 2023): Application of ISO/IEC 17021-1 for the certification of Occupational Health and Safety Management Systems (OH&SMS)*					✓			
IAF MD 23 *(Dec 2023): Control of entities operating on behalf of accredited management systems certification bodies*	✓	✓	✓	✓	✓	✓	✓	✓
IAF MD 27 *(Aug 2023): Transition requirements for ISO 22003-1: 2022*						✓		
IAF MD 28 *(okt 2023): IAF Mandatory Document for the Upload and Maintenance of Data on IAF Database*	✓	✓	✓	✓	✓	✓		
EA-7/04 M *(Rev03, May 2017): Legal compliance as a part of accredited ISO 14001:2015 certification*		✓						

✓*1 Document is in certain points (1.1-1.9, 2-7, 9-11) relevant also for these schemes, unless otherwise specified in sector-specific documents.

✓*2 In cases where the requirements for the auditing and certification of organizations with multiple sites are determined by sector-specific documents, the requirements from them have priority over the relevant requirements of this document.

3.4.3 Certification bodies for persons

- ***IAF MD 4*** *(Jun 2023): Use of Information and Communication Technology (ICT) for auditing / assessment purposes*,
- ***EA-8/01 G*** *(Apr 2024): Guidance on transfers of accredited certification of persons*.

3.5 Environmental verifiers

- ***Regulation (EC) No 1893/2006*** *of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains*, with amendments accessible on: *https://eur-lex.europa.eu/eli/reg/2006/1893*, consolidated text,
- **EA and IAF documents** used in accreditation of certification bodies **for ISO 14001** (See column 2 of the table under 3.4.2 above),
- ***Commission Decision (EU) 2016/1621*** *of 7 September 2016 adopting a guidance document on notification to accreditation and licensing bodies by environmental verifiers active in a Member State other than that where the accreditation or licence was granted under Regulation (EC) No 1221/2009 of the European Parliament and of the Council.*

3.6 Verifiers of greenhouse gas emission reports

- relevant guidance available on the EU website *Climate Action – Monitoring, reporting and verification of EU ETS emissions* (*https://ec.europa.eu/clima/policies/ets/monitoring_en#tab-0-1*):
  - ✓ ***EGD I*** *(Feb 2022): Explanatory guidance*,
  - ✓ ***KGN II.2*** *(Feb 2022): Verifier's risk analysis*,
  - ✓ ***KGN II.3*** *(Dec 2022): Process analysis*,

- ✓ ***KGN II.4*** *(Feb 2022): Sampling*,
- ✓ ***KGN II.5*** *(Dec 2020): Site visits*,
- ✓ ***KGN II.6*** *(Jan 2022): Verification report*,
- ✓ ***KGN II.7*** *(Feb 2022): Competence*,
- ✓ ***KGN II.8*** *(Mar 2022): Relation between the AVR and EN ISO 14065*,
- ✓ ***KGN II.10*** *(Jan 2022): Information exchange templates*,
- ✓ ***KGN II.12*** *(Jan 2022): Time allocation in verification*,
- ✓ ***GD III*** *(Feb 2022): Verification guidance for EU ETS aviation*,
- ✓ ***GD 4*** *(Feb 2021): Verification of FAR baseline data reports, annual activity level data and validation of monitoring methodology plans (https://ec.europa.eu/clima/system/files/2021-02/p4_gd4_verification_far_baseline_en.pdf),*

- ***EA-6/03 M*** *(Rev05, Jun 2022): EA document for accreditation of Verification Bodies for the purpose of EU ETS Directive*,
- ***IAF MD 6*** *(Nov 2023): Application of ISO 14065:2020*.

4 CHANGES SINCE THE PREVIOUS REVISION

In chapter 3.4.2, reference to document IAF MD 28 has been added.

In chapter 3.4.3, reference to document EA-8/01 G has been added.

5 TRANSITORY AND FINAL PROVISIONS

No transitory provisions. The changes in guidelines are taken into account on assessments as of the date of issue of this document.

6 CONTROL OF THE DOCUMENT

A valid copy of this document shall be located in i4 (SA's information system). A clean copy shall be published on SA's website, and available in printed form at the SA's head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies hereof shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be verified in i4 or on SA's website.