



**INSTITUTE FOR ACCREDITATION OF
THE REPUBLIC OF NORTH MACEDONIA**

**Regulation on General Requirements for the
Competence of the Conformity Assessment Bodies**

Pursuant to Article 14, paragraph 1, indent 1 of the Law on Accreditation (“Official Gazette of the RNM” no. 120/2009, 53/2011, 41/2014) and Article 13, paragraph 2 of the Statute of the Institute for Accreditation of the Republic of North Macedonia, the Council of the Institute for Accreditation of the Republic of North Macedonia at its session held on 23 February 2026, adopted the following::

REGULATION ON GENERAL REQUIREMENTS FOR THE COMPETENCE OF THE CONFORMITY ASSESSMENT BODIES

1. General provision

Article 1

This Regulation defines the basic standards, guidelines and other documents laying down the general requirements for the competence which should be fulfilled from the conformity assessment bodies as the condition for obtaining and maintaining the accreditation granted by Institute for Accreditation of the Republic of North Macedonia (further referred to as IARNM) for those fields which IARNM implement accreditation and has developed accreditation scheme .

2. General requirements for competence

2.1. Calibration Laboratories

Article 2

MKC EN ISO/IEC 17025^{*)} - General requirements for the competence of testing and calibration laboratories.

2.2. Testing Laboratories

Article 3

MKC EN ISO/IEC 17025^{*)} - General requirements for the competence of testing and calibration laboratories.

MKC EN ISO 15189^{*)} – Medical laboratories – Requirements for quality and competence.

2.3. Certification bodies for products, processes and services

Article 4

MKC EN ISO/IEC 17065^{*)} - Conformity assessment – Requirements for bodies certifying products, processes and services.

2.4. Certification bodies for management system certification

^{*)} The last version of the document

Article 5

MKC EN ISO/IEC 17021-1^{*)} – Conformity assessment – Requirements for the bodies providing audit and certification of management systems.

2.5. Inspection bodies

Article 6

MKC EN ISO/IEC 17020^{*)} - Conformity assessment - Requirements for the operation of various types of bodies performing inspection.

3. **Additional requirements**

Article 7

The additional requirements for the conformity assessment bodies are defined in the documents which are issued by IARNM, EA (European Cooperation for Accreditation), ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum). The documents are available on the web site of IARNM (www.iarm.gov.mk) and web sites of EA, ILAC and IAF (www.european-accreditation.org, www.ilac.org, www.iaf.nu) .

4. **Extending the scope of accreditation activity**

Article 8

IARNM will develop accreditation scheme in the new fields on demand of stakeholders and/or state authorities, on the basis of individual analysis and estimation of financial, personnel and other available IARNM's potential.

5. **Final provision**

Article 9

The previous Regulation on General requirements for the competence of the conformity assessment bodies adopted on the 16th of October 2015 is ceasing to have effect when this Regulation is going to become effective.

Article 10

This Regulation becomes effective at the date of its enacting.

Date: 23.02.2026

President of the Council of IARNM
Biljana Stoilovska \handwritten signature\

^{*)} The last version of the document