



**ACCREDITATION INSTITUTE OF
THE REPUBLIC OF MACEDONIA**

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

Regulation : R 04

Based on the Article 14, Paragraph 1, Indent 1 of the Law of Accreditation (Official Gazette of R, Macedonia, No. 120/09 and Article 13, Paragraph 2 of the Statute of the Accreditation Institute of the Republic of Macedonia, the Council of the Accreditation Institute of the Republic of Macedonia at the meeting held on 16.10.2015 adopted this:

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 of Accreditation of the Republic of Macedonia (further referred to as IARM) for those fields which IARM implement accreditation, scilicet IARM has developed scheme of accreditation .

2. Requirements for competence

2.1. Calibration Laboratories

Article 2

General requirements:

The standard MKC EN ISO/IEC 17025^{*)} gives the general requirements for the competence of testing and calibration laboratories.

2.2. Testing Laboratories

Article 3

General requirements:

The standard MKC EN ISO/IEC 17025^{*)} gives the general requirements for the competence of testing and calibration laboratories.

The standard MKC EN ISO 15189^{*)} gives the general requirements for the competence of medical laboratories.

2.3. Bodies certifying products, processes and services

Article 4

General requirements

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

2.4. Certification bodies operating management system certification

Article 5

General requirements:

The standard MKC EN ISO/IEC 17021^{*)} – Conformity assessment – gives the requirements for the bodies operating audit and quality managing system certification.

2.5. Personnel certification bodies

Article 6

General requirements:

The standard MKC EN ISO/IEC 17024^{*)} gives the general criteria for the certification bodies operating personnel certification.

2.6. Inspection bodies

Article 7

General requirements:

The standard MKC EN ISO/IEC 17020^{*)} gives the general criteria for the operation of various types of bodies performing the inspection.

3. **Additional requirements**

Article 8

The additional requirements for the conformity assessment bodies are defined in the documents which are issued by IARM, EA (European Cooperation for Accreditation), ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum). The documents are available on the web site of IARM (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 9

IARM will develop scheme of accreditation 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 IARM's potential.

5. **Final provision**

Article 10

The previous Regulation on General requirements for the competence of the conformity assessment bodies adopted at 29 August 2015 is ceasing to have effect when this Regulation is going to become effective.



Article 11

This Regulation becomes effective at the date of its enacting.

Date: 16.10.2015

Chairman of the Council
M-r Borce Razmoski

*) - The last version of the document