



**Regulation on cross frontier accreditation**

**Regulation: R 07**



# INSTITUTE OF ACCREDITATION OF REPUBLIC OF MACEDONIA

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Based on the Article 14, Paragraph 1, Indent 1 of the Law on Accreditation (“Official Gazette of Republic of Macedonia” No. 120/09 and 53/2011), and Article 13, Paragraph 2 of the Statute of the Institute for Accreditation of the Republic of Macedonia, the Council of the Accreditation Institute of the Republic of Macedonia at the meeting held on 24 September 2013 adopted the following

## Regulation on cross frontier accreditation

### 1. Aim

#### Article 1

The 765/2008 Directive, besides the already specified items, defines the responsibilities and the authorisations of the national accreditation body, in cases where it is required to implement the accreditation procedure of the conformity assessment body (CAB), from the EU or EFTA (European Free Trade Association) member states and the candidate countries for EU accession or EFTA, or signatories to the MLA or BLA agreement.

#### Article 2

The aim of this Regulation is to define IARM’s policy and activities in case of accreditation of CAB which has locations or which performs the key activities outside the territory of the Republic of Macedonia.

### 1. Terms and definitions

#### Article 3

CAB - Conformity Assessment Body

EA - European co-operation for Accreditation

IARM – Institute for Accreditation of the Republic of Macedonia

Cross-border accreditation - a procedure in which the Conformity Assessment Body requires accreditation from the accreditation body of another country.

FAB - Foreign Accreditation Body is an accreditation body, which accredits a CAB that has locations with key activities in a country other than the country where the accreditation body belongs.

LAT - Local Accreditation Body is the national accreditation body of the country where the accredited CAB is established. The term also applies to the accreditation body of the country in which there is a location which is involved in the accredited range of CAB, hence the accreditation is issued by the accreditation body of another country.

NAB - National Accreditation Body is the only accreditation body of a country (for instance IARM in our country, i.e. the accreditation body established by the Government of the Republic of Macedonia).

### 2. Procedure description

#### Article 4

In accordance with the standards, the European directives and the documents of EA, ILAC and IAF, IARM has the following rules and regulations relating to the cross-border accreditation:



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- IARM does not represent a competitive body to the other national accreditation bodies in the implementation of the accreditation procedure in CAB;
- IARM implements an accreditation procedure only in the CABs which are registered and domiciled in the Republic of Macedonia;
- IARM implements an accreditation procedure of CAB which is based in the Republic of Macedonia and has test sites/locations outside the territory of the Republic of Macedonia, where they perform or not key activities only in accordance with the 765/2008/EC Directive, the requirements of the MKC EN ISO/IEC 17011:2006 standard, requirements i.e. instructions listed in: EA 2/13; *EA Cross Frontier Policy for Cooperation between Members*, IAF GD 3; *Guidance on Cross Frontier Accreditation*, ILAC-G21; *Cross Frontier accreditation - Principles for Avoiding Duplication*.

## Article 5

In case of application for accreditation by CAB on the territory outside the Republic of Macedonia, IARM will comply with the above mentioned documents of EA, ILAC and IAF, and it will conduct the accreditation solely under the following conditions:

- a) in such case where the state in which the CAB is established, has not established a national accreditation body;
- b) in such case where the national accreditation body of the country in which the CAB applicant is established, has not established an accreditation scheme that covers the required accreditation area;
- c) in such case where the national accreditation body of the country in which the CAB applicant is established, is not an EA MLA signatory for the required accreditation scheme.

## Article 6

Before the commencement of any activity, IARM will demand the following from the body of the evaluation of conformity:

- a) a proof that the national accreditation body, where the CAB was legally identified, is informed about the request submitted to the IARM, for starting an accreditation procedure;
- b) a consent granted by CAB, in which IARM informs the national accreditation body about the accepted application for accreditation;
- c) evidence, i.e. statement that the request for accreditation has not been submitted to another accreditation body.



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## Article 7

If IARM decides to commence an accreditation procedure in CAB, registered outside the territory of the Republic of Macedonia, to the national accreditation body in the country where the CAB is registered, IARM will submit proposals in the capacity of observer in the accreditation procedure, or it will propose assessors from its own pool of assessors, as part of the commission for assessment by IARM, or it will propose a joint assessment to be conducted.

## Article 8

The bodies for conformity assessment, legal entities established in the Republic of Macedonia, can conduct their activities from the accredited area outside the territory of the Republic of Macedonia. For that matter, IARM should be informed earlier, through an Application for Accreditation, depending on sort of CAB involved.

## Article 9

In the course of conducting the activities outside the Republic of Macedonia by the bodies for conformity assessment, the following two scenarios are possible:

- CAB provides services for conformity assessment outside the Republic of Macedonia, and
- CABs which in their organizational scheme have separate locations on the territory of another state/s (offices, branches, etc.), and there they have implemented the key activities (listed in point 7.5.7 of the MKC EN ISO/IEC 17011:2006 standard) as part of the accredited scope.

## Article 10

When the conformity assessment body, registered as a legal entity in the Republic of Macedonia, conducts its own activities outside the borders, within the accreditation procedure and according to PR 05-08 Procedure for sampling during assessment, testimonies of all elements of the operation of the CAB under the appropriate standard are being implemented.

The cross-border accreditation should also take into account the legislation (if there is any) for the corresponding activity in the country in which the CAB performs activities and it is outside the territory of the Republic of Macedonia.

### 3. Applied documents

#### Article 11

The following documents were applied during the preparation of this Regulation:

- MKC EN ISO/IEC 17011:2006,
- EA 2/13 *EA Cross Frontier Policy for Cooperation between Members*,
- IAF GD 3 *Guidance on Cross Frontier Accreditation*,
- ILAC-G21 *Cross Frontier accreditation – Principles for Avoiding Duplication*.



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**4. Transitional and Final Provisions**

**Article 12**

This Regulation shall enter into force on the day of its adoption.

Date: 24 September 2013

President of the Council,

Borche Razmoski, M.A.