

In accordance with Article 5, paragraph 2 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No. 120/2009), the Government of the Republic of Macedonia, at the session dated 02.02.2010 adopted the following

## **WORK PROGRAM for the Institute for Accreditation of the Republic of Macedonia for 2010**

### **I. Introduction**

The Law on Accreditation ("Official Gazette of the Republic of Macedonia", No. 120/2009) shall regulate the establishment, organization and operation of the Macedonian Institute for Accreditation and act as a public institution, performing operations and tasks as a national accreditation body, and shall also regulate the procedures for accreditation on the basis of this and other laws and surveillance over the fulfillment of the accreditation requirements.

Accreditation represents a powerful tool as regards to the quality of products and development of trade relations on a national and international level, and concurrently reduced and to a greater extent eliminates the technical barriers in goods and service exchange. Accreditation is conducted upon a request by domestic and foreign legal entities, on the basis of the Law on Accreditation and other laws in compliance with the requirements of the respective Macedonian, European and international standards and documents of the national, European and international organizations.

Generally, accreditation is voluntary and in a non-discriminatory manner accessible to all parties submitting an Application for accreditation. Similarly, accreditation is the basis for acquisition of authorization by the ministries. The accreditation procedures are carried out by the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM) and particularly address accreditation of:

- Testing and calibration laboratories,
- Product certification bodies,
- Management systems certification bodies
- Inspection bodies.

The basis for the accreditation work (testing, certification and inspection) is provided in the standards of the series MKC EN ISO/IEC 17000, i.e. MKC EN 45000.

IARM actively participates in the work of the European and international organizations and represents the interests of the Republic of Macedonia therein. IARM is a full member of the European Cooperation for Accreditation (EA) and an associate member of the International Laboratory Accreditation Cooperation (ILAC).

In June 2007, the Government of the Republic of Macedonia adopted the „*Program for Inciting Investments in the Republic of Macedonia for the period 2007-2010*“ partly comprised of the IARM activities. Also, significant place of the activities envisaged in the Program for 2010 is provided in the “*Strategy for the enforcement of legislation for the respective horizontal organizations (standardization, accreditation, metrology and market supervision) in the area of free movement of goods*”, along with the Action plan, adopted by the Government of Republic of Macedonia on the 01.12.2009.

In accordance with Article 14 paragraph 1 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/2009.), for the purposes of enforcement of IARM operations and tasks, the Government of the Republic of Macedonia following a proposal by the IARM shall adopt an annual Work Program.

## II. Aims and objectives of the Work Program of the IARM for 2010

The main aim of the IARM is to establish and apply an accreditation system that will entrust the conformity bodies (certification bodies, testing and calibration laboratories and inspection bodies) with confidence in their competence and shall contribute to reducing the trade barriers of domestic products on the markets in Europe and worldwide.

Bearing in mind the fact that accreditation in the Republic of Macedonia plays a pivotal role in the internal market and quality of life and represents an important instrument in the support of the approximation of the Republic of Macedonia to the European Union which is especially stressed in the application of the harmonized legislation, the activities envisaged in this Program are specifically directed towards signing the Multilateral agreement – MLA<sup>1</sup> with the European Cooperation for Accreditation (EA). By signing this Agreement, the recognition on a European and international level of reports and certificates of accredited bodies for conformity assessment in the Republic of Macedonia shall be enabled. Meanwhile, that shall contribute to reduction of trade barriers and free movement of goods and services from the Republic of Macedonia.

IARM shall direct majority of its activities in 2010 to the actual signing of the MLA. Namely, in the period of 07 to 11 December 2009, the MLA pre-assessment team has delivered the pre-assessment visit and submitted the Pre-assessment Report. In 2010, the IARM shall strive towards full enforcement of the recommendations provided in the Report which also act as **objectives** in the implementation of the Program as follows:

- Management and coordination of the accreditation activities in the Republic of Macedonia pursuant to the European and international principles and practices,
- Promotion of reports and/or certificates issued by the conformity assessment bodies accredited by the IARM and commitment to signing of the Multilateral agreement within the EA,
- Development of an adequate accreditation process and practice based on the European and international standards and guidelines;
- Active cooperation with the European and international accreditation organization;
- Continuous commitment in facilitation of global trade by way of acceptance of outcomes of the accredited bodies for conformity assessment,
- Providing technical support to the ministries in the implementation of the Directives and
- Continuous work for acquiring greater trust by interested parties.

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<sup>1</sup> MLA is an agreement signed among the accreditation bodies, members of the EA, for recognition of equality and confidentiality and thus acceptance of accredited certification, inspection and calibration certificates and testing reports across Europe.

### **III. Envisaged activities for the realization of the Program**

The Budget of the Republic of Macedonia for 2010 ("Official Gazette of the Republic of Macedonia" No.156/2009), section 10001 – Ministry of Economy, in the subprogram 51 – IARM, categories 42 – goods and services 48 – capital expenditure has planned funds in the amount of 9.078.000 MKD.

For the establishment and maintenance of an efficient National accreditation system in accordance with the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/2009), the standard MKC EN ISO/IEC 17011, as well as the recommendations by the international team for signing the MLA with the European Cooperation for Accreditation, the following activities should be carried out:

#### **1. Accreditation activities**

IARM has so far accredited 45 conformity assessment bodies and has 20 new pending applications for accreditation. In 2010 a regular supervision over the accredited bodies will be carried out and IARM shall strive towards increase of the number of accredited bodies for conformity assessment.

In accordance with the new Law on Accreditation (enforced since 02.10.2009) as well as with the Report from the MLA pre-assessment team, the IARM shall continuously improve the overall accreditation system, and especially implement activities in the following areas:

- In 2010 shall adopt the new Statute of the IARM and amend and complement all the remaining internal acts (procedures and regulations/ rulebooks).
- Within the development activities, IARM shall prepare new accreditation schemes in accordance with the specific needs of the Republic of Macedonia. The development of these schemes shall be in cooperation with the technical committees.
- The start of operation of the sector committees whose basic task shall be to develop documents which will assist the procedure for assessment of the conformity assessment body competencies conformant to the existing regulation.
- Procurement of Data Management Software. The total procurement funds for the Software ranged in the amount of EUR 90.000 and have been secured via the project BERIS (World Bank loan to the Government of the Republic of Macedonia). The above stated funds have been calculated in the budget of the Ministry of Economy as holder of the project. The procurement of this software is a prerequisite for start of activities envisaged in the IPA national project.

Under the cooperation with the national institutions, IARM shall sign a bilateral cooperation agreement with the Ministry of Economy regulating the mutual relations in the area of quality infrastructure in the Republic of Macedonia. Also, IARM shall actively cooperate with the Institute for Standardization in the Republic of Macedonia and the Bureau of Metrology, institutions already signatories of the cooperation agreements with IARM.

| **Necessary funds ..... 4.000.000 MKD**

## 2. Organization of training

Under this activity, IARM needs to organize training for its employees as well as for the external associates in order to expand the number of assessors used by the IARM in the accreditation procedures.

The list of assessors of IARM is composed of 16 lead assessors, 61 assessors as well as 44 experts. In line with the recommendations from the pre-assessment for the MLA signing, an additional training of registered assessors is required and expansion of the list of assessors and experts from all areas represented in the accreditation procedures.

In 2010 the IARM shall organize the following:

- Training for assessors on standards: MKS EN ISO/IEC 17025, MKS EN ISO/IEC 17024, MKS EN ISO/IEC 17020, MKS EN ISO/IEC 17021 and MKS EN 45011.
- Seminars for development of new accreditation schemes such as: *Accreditation of medical laboratories*  
*Accreditation of personnel certification bodies*  
*Accreditation of certification bodies for food safety management systems, environment management etc.*
- Two seminars organized by TAIEX:  
*Accreditation role in implementation of the Regulation (EC) 765/2008*  
*IARM Communication with National Regulators*

In addition to the training independently organized by the IARM, in 2010, IARM will organize training under the project with the German society for technical cooperation (GTZ); and these training shall be mainly intended for the inspection bodies.

The training will be organized in the Training center of the IARM which is to be additionally equipped in order to attain full functionality.

**Necessary funds..... 1.500.000 MKD**

## 3. Promoting the accreditation system

Accreditation as a procedure is more frequently represented in national legislation and the accreditation requirements upon institutions in the country are significantly imposed. For that purpose, greater familiarization of interested parties is required as to both the manner of application as well as the method of attaining accredited body status.

Within the activities of promotion of the accreditation system, the IARM shall undertake the following activities:

- Preparation and issuance of promotional and educational material in the area of accreditation
- Promotion of granting certificates to accredited bodies in 2009. This promotion event will be organized in March 2010.

**Needed funds ..... 700.000 MKD**

#### **4. The work of the IARM Council and the Supervisory Board for Material and Financial Control**

The IARM Council is composed of 11 members whereas the Supervisory Board for Material and Financial Control of three. The meetings of the two bodies operating under the IARM are organized when necessary and payment is conducted upon attendance to not more than 12 meetings per annum.

**Necessary funds ..... 1.300.000 MKD**

#### **5. International activities**

As a full member of the EA, IARM, by sending representatives, shall mandatorily participate in the two annual EA Assembly meetings and in the two MAC Committee meetings (EA - Multilateral Agreement Committee) which are to be organized in 2010.

Similarly, in order to keep up with the latest trends in the area of accreditation in Europe, it is necessary to send IARM representatives at the meetings of the committees of the European Cooperation for Accreditation (Laboratory Committee, Certification Committee, Inspection Committee, Communication and Publication Committee).

In order to attain a successful MLA peer evaluation which is to be conducted by a team of assessors mandated by EA, the participation of the IARM personnel to these events will be of great importance.

For the purposes of continuation of the international affirmation of the IARM, attendance of one IARM representative to the ILAC annual Assembly meeting in 2010 is envisaged.

On a regional level IARM has signed bilateral agreements for cooperation with the national accreditation authorities of Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey and Kosovo. In 2010, the IARM plans to sign a bilateral agreement for cooperation with the accreditation authority in Bosnia and Herzegovina. The purpose of these agreements is to organize shared assessors trainings, exchange of experts and assessors on a regional level which will contribute towards designing an efficient accreditation system.

**Needed funds ..... 1.578.000 MKD**

The Institute for Accreditation of the Republic of Macedonia by 31.01.2011 inclusive, shall submit to the Government of Republic of Macedonia a Report containing financial indicators for the performance of the Work Program of the Institute for Accreditation of Republic of Macedonia for 2010 enclosing the attained outcomes and financial indicators as well as elaboration on potential divergence from the planned and envisaged activities.

This Program shall enter into force the day following the publication in the "Official Gazette of Republic of Macedonia".

**Number:19-6836/1-09**

**Date: 2 February 2010**

**Skopje**

**Government of the Republic of  
Macedonia**

**Deputy Prime Minister  
Zoran Stavreski MSc**