

On the basis of 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 on the session held on the 05.01.2011 adopted the following

## **Work Program of the Institute for Accreditation of the Republic of Macedonia for the year 2011**

### **I. Introduction**

The Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/2009) shall regulate the constitution, organization and operation of the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM) as a public institution performing tasks and activities of a national accreditation body, as well as regulate the procedure for accreditation pursuant to this and other laws and supervision over the fulfillment of requirements of accreditation.

Accreditation represents a powerful tool as regards to the quality of products and development of trade relations on a national and international level. Concurrently, accreditation reduces and to a greater extent eliminates the technical barriers in goods and service exchange. Accreditation contributes to a better quality and improved competitiveness of low cost products and services. Accreditation is conducted upon a request by domestic and international 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 IARM and particularly address accreditation of:

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

Procedures for accreditation (in the area of testing, certification and inspection) are based on the standards in the series MKS EN ISO/IEC 17000, or MKS EN 45000.

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

Pursuant to Article 14 paragraph 1 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia" No. 120/2009) for the purposes of enforcing tasks and activities of the IARM, the Government of Republic of Macedonia following a proposal by the IARM adopts an Annual Work Program.

### **II. Aims of the Work Program of the IARM for 2011**

**The primary aim** of the IARM is continuous strengthening of the 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 across the globe.

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 EA. By signing this Agreement, the recognition on a European and international level of reports and certificates of accredited conformity assessment bodies 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 2011 towards the actual signing of the MLA. Namely, in the period of 07 to 11 December 2009, the MLA pre-assessment team carried out the pre-assessment visit and submitted the Pre-assessment Report. In 2010, the IARM fully implemented the recommendations from the Report and during 2011 the peer evaluation by the MLA assessment team is expected:

Work Program **objectives** are as follows:

- Strengthening 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
- Development of an adequate accreditation process and practice based on the European /international standards and guidelines;
- Active cooperation with the European and international accreditation organization;
- Continuous commitment to facilitation in global trade by way of acceptance of outcomes of the accredited conformity assessment bodies,
- Providing technical support to the ministries in the implementation of the Directives and
- Continuous work for acquiring greater trust by interested parties.

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

The Budget of the Republic of Macedonia for 2011 (“Official Gazette of the Republic of Macedonia” No.161/2010), section 10001 – Ministry of Economy, in the subprogram 51 – IARM, categories 42 – goods and services and 48 – capital expenditure, has planned funds in the amount of 22,494,000 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 MKS EN ISO/IEC 17011, as well as the recommendations by the international team for signing the MLA with the EA, the following activities need to be carried out:

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

IARM has so far accredited 60 conformity assessment bodies and has 27 new pending applications for accreditation. In 2011 a regular surveillance over the accredited bodies will be carried out and IARM shall strive towards increase in the number of accredited conformity assessment bodies.

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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

In accordance with the new Law on Accreditation as well as with the Report from the MLA pre-assessment team, the IARM shall continuously improve the overall accreditation system adapted to the specific needs of the Republic of Macedonia. The development of these schemes shall be in cooperation with the interested parties, supported by the work of the Technical Committees.

In the course of delivery of accreditation activities, the work of the Sector Committees shall take a significant role whose basic task is preparation of documents aiding the procedure for competence assessment of the conformity assessment bodies pursuant to identified regulation.

Considering the fact that the competence of the assessors shall be considered as key for qualitative delivery of accreditation activities, the IARM, in its operation shall place great emphasis on engaging assessors with needed expertise and experts of various technical fields as well as on their training/further training on standards for accreditation and assessment procedures.

The assessors and experts lists shall be continuously complemented with new names and regularly updated. In 2010 the Assessors List was comprised of 55 assessors, of which 17 leading assessors, 48 candidates for assessors and 50 experts. Ten of the leading assessors are employees professionals in the IARM, whereas the rest are external associates the majority from the Republic of Macedonia. The list, in addition contains international assessors and experts from other accreditation bodies, members of the EA or those having signed Cooperation Agreements with the IARM.

Under the cooperation with the national institutions, IARM shall sign a bilateral cooperation agreement with the Ministry of Economy. The Contract shall regulate 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 ..... 3,000,000 MKD**

## **2. Signing of Multilateral Agreement (MLA)**

In the period between the 17<sup>th</sup> and 21<sup>st</sup> December 2009 the pre-assessment visit of IARM took place as a part of the MLA signing procedure. The pre-assessment visit was carried out by an international EA team. During 2010, IARM fully eliminated all remarks laid down in the pre-assessment visit report and in 2011 the peer evaluation by the EA is expected. The peer evaluation shall be conducted by a team of 5 experts proposed by the EA and the full financial cost of the assessment thereof shall be covered by the IARM.

The signing of this contract is of particular importance to the Macedonian economy since this contract shall assign the Macedonian companies an equal status with the European and international companies in their markets.

**Necessary funds ..... 500,000 MKD**

## **3. Organization of training**

Under this activity, IARM shall 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.

In 2011, the IARM shall strive towards expanding the number of leading assessors by engaging the candidates for assessors and the technical assessors in the theoretical training sessions and training by their engagement into the supervised assessments.

In accordance with the recommendations from the MLA pre-assessment visit, in 2010 further training of registered assessors was initiated and the list of assessors and experts were expanded in all areas represented in the accreditation procedures.

In 2011 the IARM shall carry on this trend and for such that purpose shall organize the following:

- Training for assessors on the standard MKS EN ISO/IEC 17011- General requirements for the accreditation bodies accrediting conformity assessment bodies, standard adhered to by the IARM. This training is necessary to provide understanding of the quality system in all levels of organization of the IARM. During the training, in addition to the requirements of the Standard, documents of the quality system of the IARM as well as elements of the standard ISO 19011 shall be presented. Similarly, this training shall expand the number of internal auditors in the IARM. This training shall take part on the 21<sup>st</sup> and 22<sup>nd</sup> January 2011.
- Training for assessors on standards: MKS EN ISO/IEC 17025 and MKS EN ISO/IEC 17020.
- Training and or workshops on specific technical requirements (such as uncertainty of measurement, utilization of reference materials etc.)
- Seminars for development of new accreditations schemes:  
*Accreditation of medical laboratories*  
*Accreditation of personnel certification bodies*

These training sessions shall be attended by the IARM staff and the external associates, assessors and experts.

Some of the theoretical training shall be organized in the IARM Training Centre, some in the international accreditation bodies, members of EA, signatories of the MLA.

Within the IPA 2008 Project for 2011, training and study visits are also envisaged. Part of the training shall be theoretical (training of trainers and assessors) whereas the majority shall be on-site training through exchange of experiences with EA assessors acting as partners by organizing supervised assessments of international assessors and the like.

**Necessary funds ..... 600,000 MKD**

#### **4. 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
- Issuance of Annual Work Report of the IARM for 2010.
- Promotion of granting certificates to accredited bodies in 2011. This promotion event will be organized on the 9<sup>th</sup> June 2011 on the International Accreditation Day.
- Protection of the logo and accreditation mark in the State Office of Industrial Property.

**Necessary funds ..... 300,000 MKD**

## **5. The work of the IARM Council and the Material and Financial Control Supervision Board**

The IARM Council is composed of 11 members whereas the Material and Financial Control Supervision Board 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..... 1,000,000 MKD**

## **6. 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 2011. 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 EA (Laboratory Committee, Certification Bodies Committee, Inspection Bodies Committee, Communication and Publication Committee, Horizontal Harmonization Committee).

In order to attain a successful peer evaluation for the signing of the MLA 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 continuation of the international affirmation of the IARM, one representative of the IARM is envisaged at the annual ILAC Assembly in 2011.

On a regional level IARM has signed bilateral agreements for cooperation with the national accreditation authorities of Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo and 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

**Necessary funds ..... 1,094,000 MKD**

## **7. Implementation of the “IPA-2008“ Project**

Name of the project: *Support of Free Movement of Goods – Quality Infrastructure*, Component – Support to the Institute for Accreditation.

Basic objectives of the Project are increase in the number of technical assessors, improvement of the management system documentation, international recognition of testing and certification reports and implementation of the Directives of the New, Global and Old Approach-increase in the number of notified conformity assessment bodies.

The aforementioned objectives are to be realized by the IARM via shared assessments with an MLA signatory accreditation body, of Macedonian laboratories, inspection and certification bodies, organizing training, transfer of knowledge and application of best practices in the EU member countries for accreditation of notified bodies. Also, under the Project, software for data management shall be procured as an aid to the process of assessment of competence of conformity assessment bodies. Funds for software procurement are allocated by the Budget of the IARM and represent national co-financing for the implementation of the Project.

**Necessary funds ..... 15,300,000 MKD**

#### **8. Management and current operation of the IARM**

The IARM Director's mandate expires November 2011, therefore in October 2011 a procedure for election of a new IARM's Director shall be initiated.

In respect of the operations of the Financial Section, procurement of software for treasury operations is needed. Similarly, for the regular continuation of IARM's activities, the IARM budget of 2011 shall allocate funds for reconstruction of the Training Center as well as for the procurement of computer and telecommunication equipment.

**Necessary funds ..... 700,000 MKD**

The Institute for Accreditation of the Republic of Macedonia by 31.01.2012 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 2011 enclosing the attained outcomes and financial indicators as well as elaboration on potential divergence from the planed and envisaged activities.

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

**No.51-7935/1-10  
5 January 2011  
Skopje**

**Deputy President of the  
Government of the Republic of  
Macedonia  
d-r Vasko Naumovski**

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