

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 09.01.2012 adopted the following

Work Program of the Institute for Accreditation of the Republic of Macedonia for the year 2012

I. Introduction

The Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/2009 and No.53/2011) shall regulate the constitution, organization and operation of the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM) as one of 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, in accordance with the Law on Accreditation and other laws, and 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 Accreditation Application. Similarly, accreditation is the basis for acquisition of authorization by the ministries. The accreditation procedures carried out by the IARM particularly address the 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 and No.53/2011) 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 2012

The primary aim of the IARM is continuous strengthening of the accreditation system and so obtaining confidence in the competence of the conformity assessment bodies (certification bodies, testing and calibration laboratories and inspection bodies) and shall contribute to reducing the trade barriers of domestic products in the markets of 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 particularly stressed in the application of the harmonized legislation, the activities envisaged in this Program are specifically directed towards signing the Multilateral agreement – MLA¹ of accreditation certificates with the EA. The signing of this Agreement will bring about the recognition on a European and international level of reports and certificates of accredited conformity assessment bodies in the Republic of Macedonia. 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 2012 towards the actual signing of the MLA. Namely, in the period between the 24th and 28th October 2011, the MLA pre-assessment team carried out the pre-assessment visit and submitted the Pre-assessment Report. In 2012, the IARM will have fully implemented the recommendations from the Report and in May 2012, in the course of the European cooperation for Accreditation General Assembly meeting, IARM is expected to sign the Multilateral Agreement with the European cooperation for Accreditation. (EA).

Work Program **objectives** are as follows:

- Increase in the number of accredited bodies by the IARM
- Institutional strengthening and coordination of the accreditation activities in the Republic of Macedonia by expanding the number of technical assessors and experts,
- Continuous efforts invested in facilitation of global trade by accepting the results of the accredited conformity assessment bodies,
- Promotion of reports and/or certificates issued by the conformity assessment bodies accredited by the IARM
- Implementation of all Government projects related to the operation of the IARM
- Provision of technical support to ministries and respective institutions on all affairs related to the accreditation procedures,
- Active cooperation with the European and international accreditation organization;
- Continuous work for acquiring greater trust by interested parties.

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

III. Envisaged activities for enforcement of the Program

The Budget of the Republic of Macedonia for 2012 ("Official Gazette of the Republic of Macedonia" No.180/2011), 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 10,439,000.00 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 and 53/2011), 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 91 conformity assessment bodies and has 27 new pending applications for accreditation. In 2012 a regular supervision over the accredited bodies will be carried out and IARM shall strive towards increase in the number of accredited conformity assessment bodies.

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. Within the activities for development, the IARM shall develop new accreditation schemes pursuant to the specific needs of Republic of Macedonia such as the accreditation of medical laboratories, accreditation of certification bodies for systems, personnel etc. The development of these schemes shall be concurrent and in cooperation with the interested parties, supported by the work of the Technical Committees.

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

In order to conform to the requirements of the accreditation standards, around 30% of the engaged technical assessors and experts in enforcement of accreditation procedures will come from abroad.

Under the cooperation with the national institutions, IARM shall sign a Bilateral Cooperation Agreement with the Ministry of Economy. The Agreement 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 cooperation agreements with IARM.

Necessary funds 6,000,000.00 MKD

2. Signing of Accreditation Certificates Multilateral Agreement (EA- MLA)

In the period between the 17th and 21st 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 the period between 23rd and 29th October 2011, the peer evaluation by the EA was carried out. The peer evaluation was conducted by a team of 4 experts nominated by the EA followed by submission of a Peer Evaluation Report. The Report of the peer evaluation was positive, and the IARM shall strive towards elimination of enclosed remarks in the shortest possible time. Pursuant to the EA procedures, the Peer

Evaluation Report shall be put to vote at the EA- Multilateral Agreement Committee, at a regular meeting to be held in April 2012; whereas the signing of the EA-MLA should take place in May 2012 at the meeting of the EA General Assembly.

The signing of this Agreement is of particular importance to the Macedonian economy since this Agreement shall assign the Macedonian companies equal status to the European and international companies in the respective international markets. Similarly, the signing of this Agreement shall be considered key to the implementation of the project by the Government of Republic of Macedonia entitled "Macedonian Sun".

Necessary funds 300,000.00 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 2012, the IARM shall strive towards expanding the number of leading assessors by engaging the candidates for assessors and technical assessors in the theoretical training sessions and training by engaging them into the supervised assessments.

The assessors and experts lists shall be continuously complemented with new names and regularly updated. In 2011 the Assessors List was comprised of 21 technical assessors, 16 leading assessors, 22 assessors in training, 6 candidates for assessors and 31 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 lists, in addition contain assessors and experts from other accreditation bodies, members in the EA or those having signed Cooperation Agreements with the IARM.

In 2012, the IARM shall organize the following training:

- 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;
- Training for leading assessors on standards: MKS EN ISO/IEC 17025 and MKS EN ISO/IEC 17020;
- Training for assessors on new/revised standards: MKS EN ISO/IEC 17065, : MKS EN ISO/IEC 17021, : MKS EN ISO/IEC 17020;
- Training of trainers;
- Training and or workshops on specific technical requirements (such as traceability of measurement, uncertainty of measurement, utilization of reference materials etc.)
- Training for development of new accreditations schemes:
Accreditation of medical laboratories (MKS EN ISO/IEC15189)
Accreditation of personnel certification bodies (MKS EN ISO/IEC 17024)

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.

Necessary funds 600,000.00 MKD

4. Promoting the accreditation system

Pursuant to the conclusions of the Fifth and Twenty-first session of the Government of Republic of Macedonia, the IARM, in cooperation with the Ministry of Economy shall undertake activities in favor of promotion of the need of accredited and authorized bodies with head offices in Republic of Macedonia. The promotion of the accreditation system shall be pivotal to the implementation of the Project "Macedonian Sun" by the Government of Republic of Macedonia, accordingly foreseeing all Macedonian exported products to be analyzed by the laboratories accredited by the IARM.

For the purposes of full enforcement of the aforesaid conclusions, greater familiarization as to both the manner of application and the method of attaining accredited body status shall be required. Therefore, upon signing of the EA-MLA, the IARM shall organize a series of promotion events introducing the benefits of the Contract to all interested parties.

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

- Organization of shared events with the Consumers Organization of the Republic of Macedonia;
- Organization of events with the Chambers of Commerce of the Republic of Macedonia;
- Organization of events with businessmen in cities across the territory of Republic of Macedonia;
- Organization of a press-conference
- Preparation and issuance of promotional and educational material in the area of accreditation
- Issuance of Annual Work Report of the IARM for 2011.
- Promotion of granting certificates to accredited bodies in 2012. This promotion event will be organized on the 9th June 2012 on the International Accreditation Day.
- Protection of the logo and accreditation mark in the State Industrial Ownership Office.

Necessary funds 600,000.00 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 members. 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..... 1,000,000.00 MKD

6. International activities

As a full pledged member of the EA, and particularly in support of signing of the MLA, the 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 2012. 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).

For continuation of the international affirmation of the IARM, one representative of the IARM is envisaged at the annual ILAC General Assembly meeting in 2012.

At a regional level IARM has signed Bilateral Cooperation Agreements with the national accreditation authorities of Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo and Bosnia and Herzegovina and Moldova. 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 1,039,000.00 MKD

7. Implementation of the “IPA-2008“ Project

Name of the project: “Technical assistance for institutional strengthening of the Institute for Accreditation.” The Project was launched on the 1st February 2011 and is envisaged to last until 30 July 2012. The Consortium of the Project is composed of the Federal Institute for Materials Research and Testing (BAM – Germany), the German accreditation authority (DAkkS) and the Lithuanian National Accreditation Bureau (LA).

Basic objectives of the Project are increase in the number of technical assessors, improvement of the management system documentation, procurement of data management software, 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 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.

Under the Project in 2012, training and study visits are also foreseen. Part of the training sessions shall be theoretical (training of trainers and assessors) and most shall be on-site trainings through exchange of experiences with EA assessors acting as partners, through organizing assessment under supervision of international assessors and the like.

Necessary funds 300,000.00 MKD

8. Management and current operation of the IARM

For the regular delivery of IARM’s activities, the IARM Budget for 2012 shall allocate funds for maintenance of hardware and software equipment, maintenance of the Training Center as well as procurement of computer equipment.

Necessary funds 600,000.00 MKD

The Institute for Accreditation of the Republic of Macedonia by 31.01.2013 inclusive, shall submit to the Government of Republic of Macedonia a Report containing financial indicators for the delivery of the Work Program of the Institute for Accreditation of Republic of Macedonia for 2012 enclosing the achieved outcomes and financial indicators as well as elaboration on potential divergence from the planed and envisaged activities.

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

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Skopje

President of the Government of the
Republic of Macedonia
Nikola Gruevski, MSc
