



**INSTITUTE FOR ACCREDITATION OF THE
REPUBLIC OF MACEDONIA**

**WORK PROGRAM
of the Institute for Accreditation
of the Republic of Macedonia for the year 2013**

Act: PR 2013

On the basis of Article 5, paragraph 2 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/2009 and 53/11), the Government of the Republic of Macedonia on the session held on the 03th January 2013 adopted the following

Work Program of the Institute for Accreditation of the Republic of Macedonia for the year 2013

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 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 the requirements for accreditation.

Accreditation represents a powerful tool, thus directly providing for the quality of products and development of trade relations on a national and international level. The core of accreditation is to strive towards greater quality and competitiveness of products and services at a reduced cost. Under the auspices of accreditation and above all due to the advantages offered by its system of requirements, the manufacturers are increasingly oriented towards raising the quality of offered products and services, thus reducing the potential for standard production error. Similarly, through the Law on Accreditation, most of technical barriers during exchange of goods and services are decreased if not eliminated, thus demonstrating its role of support to industry and international trade.

This benefit to our economy has been earned by the IARM through the accreditation activity, by being granted recognition for fulfillment of the specific requirements and conditions stipulated in international agreements.

Namely, by the signing of the Multilateral Agreement with the European cooperation for Accreditation – EA-MLA and with the International Laboratory Accreditation Cooperation ILAC-MRA, the IARM opened the gates to the European and world market following the principle "accredited once, accepted everywhere". The signing of the Agreements shall mean that the issued documents by the Macedonian accredited conformity assessment bodies, in accordance with the Standards MKS EN ISO/IEC 17025 for testing and calibration laboratories, MKS EN ISO/IEC 17020 for inspection bodies and MKS EN 45011 for process, product and service certification bodies shall be globally recognized.

More specifically, the signing of the Multilateral Agreement with the European cooperation for Accreditation (EA-MLA¹) shall mean that starting from April 2012, all issued certificates and reports by the accredited Macedonian bodies (testing and calibration laboratories, inspection and certification bodies) shall be equally valid and legitimate in the European market.

¹MLA is an agreement signed between the EA accreditation body members to recognize the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports across Europe.

The signing of this Agreement led to the signing of the second important international agreement- Multilateral Recognition of Accreditations Agreement for Testing, Calibration and Inspection with the International Laboratory Accreditation Cooperation (ILAC-MRA²), recorded as another international achievement of the IARM.

The benefits of signing of both Agreements have already been felt by the companies, since by the means of such agreements the trade barriers have been lessened and free movement of goods and services from Republic of Macedonia to international markets enabled. Namely, once tested/certified product or service from an accredited body in the country can be freely exported abroad, without being subject to repeated attestation.

The accreditation procedure is carried out upon request by national and international legal entities and is grounded in the provisions of the Law on Accreditation and other legislation in accordance with the requirements of the respective Macedonian, European and international standards and documents of the national, European and international organizations.

Basically, accreditation is voluntary and in a non-discriminatory manner accessible to all clients that submit an Application for Accreditation. Similarly, accreditation is the grounds for obtaining authorization from numerous ministries. The accreditation procedures carried out by the IARM shall specifically refer to accreditation of:

- Testing and calibration laboratories;
- Product certification bodies;
- Management system certification bodies and
- Inspection bodies

The accreditation procedures (in the areas of testing, certification and inspection) are grounded in the standards of the series MKS EN ISO/IEC 17000, i.e. MKS EN 45000.

IARM actively participates in the work of the European and international accreditation organizations and therein represents the interests of the Republic of Macedonia. IARM is a full-fledged member of the European cooperation for Accreditation – EA and the International Laboratory Accreditation Cooperation - ILAC.

In accordance with Article 14, paragraph 1 of the Law on Accreditation (“Official Gazette of the Republic of Macedonia”, No. 120/09 and 53/11), for the purposes of carrying out the tasks and activities of the IARM, the Government of the Republic of Macedonia, following a proposal by the IARM, adopts an annual work program.

II. Aims of the Work Program of the IARM for 2013

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 concurrently facilitating free trade of domestic products to the European and global markets.

²MRA is an agreement signed between the ILAC accreditation body members to recognize the equivalence, reliability and therefore acceptance of accredited inspection and calibration certificates and test reports across Europe

Accreditation, in Republic of Macedonia and across the world plays a pivotal role in the strengthening of internal markets and quality of life and its role lays primarily in the development of the domestic economy and its global integration. Additionally, for Republic of Macedonia accreditation is an important instrument in the support of the approximation of the Republic of Macedonia to the European Union, which is particularly stressed in the enforcement of the harmonized legislation, i.e by the fulfillment of the requirements for aligning of the national with the European legislation, and strengthening of the institutional capacities for the implementation of the European legislation. The very signing of the two international Agreements means recognition of the fulfillment of the requirements for application of the technical legislation.

Taking into account such benefits from the implementation of the previously set out plans and aims of the IARM, that represent acknowledgment for the successful performance of the accreditation activity, as well as their potential, one must also consider their multipurpose. Namely, on one hand the signing of the Agreements shall mean recognition of the established accreditation system in the Republic of Macedonia, imposing the primary obligation for its additional maintenance and upgrade as well, and on the other shall mean expansion of national entities seeking accreditation, thus directly leading towards increased work scope of the IARM.

The signing of the two international agreements refers to another new aspect of IARM's work, in the area of cross border accreditation. By becoming the signatory of the MLA and MRA, the IARM acquired the privilege to perform accreditation abroad, on international entities, not residential to Republic of Macedonia, and at locations in countries, which are not signatories of these Agreements.

Therefore, the main activities of the IARM in 2013 shall be directed towards preparing for the first surveillance visit by the EA, as a follow up to the signing of the EA-MLA Agreement. In accordance with the rules, plans and work program of the European cooperation for Accreditation, the first surveillance visit should be carried out in October 2013.

Objectives for the enforcement of the Program are as follows:

- Increase in the number of accredited bodies by the IARM, nationally and internationally;
- 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 Government projects related to the operation of the IARM;
- Implementation of the project “Makedonsko soncence” (Macedonian Sun);
- 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 winning and keeping the trust of the interested parties and
- Continuation of the established cooperation with the Economic Chambers of the Republic of Macedonia, the Consumers' Organization of Macedonia and the economic operators.

III. Envisaged activities for enforcement of the Program

The Budget of the Republic of Macedonia for 2013 ("Official Gazette of the Republic of Macedonia" No167 /2012), 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 14,036,000.00 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 rules of the European cooperation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC), the following activities need to be carried out:

1. Accreditation activities

IARM has so far accredited 112 conformity assessment bodies and has 27 new pending applications for accreditation. In 2013 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.

In accordance with the new Law on Accreditation as well as the obligations arising from the signed international agreements, the IARM shall continuously maintain and improve the overall accreditation system. Within the activities for development, the IARM shall develop new accreditation schemes pursuant to the specific needs of the Republic of Macedonia, such as the accreditation of certification bodies for systems, personnel etc., whereas the development of new schemes for accreditation of medical laboratories has already started. 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 is considered key for qualitative delivery of accreditation activities, the IARM, in its operation, places great emphasis on engaging technical assessors and experts of various technical fields; also focuses 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 delivery of accreditation procedures will come from abroad. However, in future, the IARM shall attempt to strengthen the competency of the domestic assessors and experts by the means of their engagement and training in order to increase their commitment in the accreditation procedures.

Under the cooperation with national authorities, with whom bilateral agreements have been signed, the IARM shall actively continue to cooperate with the Ministry of Economy, the Institute for Standardization of the Republic of Macedonia and the Bureau for Metrology.

Necessary funds..... 6,000,000.00 MKD

2. First regular surveillance visit following the signing of the Multilateral Agreement with the European cooperation for Accreditation (EA-MLA)

In accordance with the rules, the plans and work program of the European cooperation for Accreditation (EA), the first regular surveillance visit upon signing of the Multilateral Agreement with the European cooperation for Accreditation (MLA-EA) shall be carried out in October 2013. Procedurally, the surveillance visit should take place two years following

the peer evaluation visit (October 2011). The forthcoming surveillance visit shall be carried out by an international team comprised of five members delegated by the EA, whereas the overall organization and costs shall be borne by the IARM (travel costs, food and accommodation expenses).

Sustaining validity of the Agreement, through presentation and defense of the established accreditation system and meeting the obligations arising thereof through variety of activities is essential not only to the activity scope of the IARM and the Macedonian economy, but to the delivery of the project of the Government of the Republic of Macedonia- “Makedonsko soncence” (“Macedonian Sun”).

Necessary funds 500,000.00 MKD

3. Organization of training

Maintaining and upgrading the competence of the staff of the IARM as well as of the external associates in order to expand the number of assessors utilized by the IARM for the accreditation procedures, is a necessity, however a primary obligation as well for the IARM resulting from the international agreement. Hence, the forthcoming year shall also bear particular emphasis on organization of and participation in training, seminars and workshops.

In 2013, the IARM shall strive towards expanding the number of leading assessors by engaging the candidates for assessors and technical assessors in the theoretical training and training by engaging them into the supervised assessments. Throughout, particular consideration shall be put into a more intense engagement of domestic assessors and experts for the purposes of implementation of the accreditation procedures. Unfortunately, thus far experience showed a deficiency in domestic experts for particular fields that meet the criteria so as to be recruited by the List of Assessors of the IARM, as a result of which the IARM was forced to engage foreign assessors. The very organization of specific training enables eligibility to enroll into the lists of assessors and experts, and upgrade it by enlisting new individuals whose data shall be regularly updated.

In 2012, the list of assessors was comprised of 16 leading assessors, 32 technical assessors, 15 assessors in training, 6 candidates for assessors and 34 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 2013, 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 for testing and calibration laboratories and MKS EN ISO/IEC 17020 for inspection bodies;
- Training for assessors on new/revised standards: MKS EN ISO/IEC 17065 and MKS EN ISO/IEC 17024 for certification bodies, MKS EN ISO/IEC 17020 for inspection bodies;
- Training of trainers;
- Training and/or workshops on specific technical requirements (such as traceability of measurement, uncertainty of measurement, utilization of reference materials etc.) and
- Training for development of new accreditations schemes:

Accreditation of medical laboratories (MKS EN ISO/IEC 15189) and

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. Performing internal audit

In accordance with the requirements of the Standard MKS EN ISO/IEC 17011, the performance of the regular internal audit for the staff of the IARM is a compulsory task and a necessity for maintenance and upgrade of the quality system in the IARM.

5. Management review

In accordance with the Quality Policy and Work Procedures of the IARM, once a year, a review of the management of the IARM (the Director, the Chairperson of the Council, the Quality Manager, Heads of Departments and Units) is carried out.

The purpose of the management review is through analysis of documents, reports, complaints, appeals, remarks and non-conformities to define and redefine the policies and aims of the IARM and to examine the efficiency of the quality system of the IARM.

6. Promoting the accreditation system

Pursuant to the continuous recommendations by the Government of the 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 the 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 recommendations, greater familiarization as to both the manner of application and the method of attaining accredited body status shall be required. Similarly, upon signing of the international agreements EA-MLA, and ILAC-MRA, the IARM shall organize new promotional events familiarizing all interested parties as to the benefits and advantage of signing these Agreements.

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

- Organization of joint events with the Consumers’ Organization of the Republic of Macedonia
- Organization of joint events with the Economic Chambers of the Republic of Macedonia;
- Organization of press conferences;
- Preparation and issuance of promotional and educational material in the area of accreditation, on topics recommended by the European and global accreditation organization: “*Why use services from an accredited laboratory*”, “*The need to be an*”

accredited laboratory and the advantages of the acquired status of an accredited laboratory”, “How does using an accredited laboratory benefit the Government and regulators”.

- Preparation of an Annual Work Report for the year 2012;
- Ceremony of awarding of certificates to accredited bodies in 2013. This promotional event shall take place on the 9th June 2013, on the World Accreditation Day;
- Commemorating the 10 year anniversary of the founding of the IARM (2003-2013) and
- Protection of the logo and the accreditation sign in the Industrial Property Protection Office

Necessary funds 600,000.00 MKD

7. 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 and limited to not more than 12 fees per annum.

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

8. International activities

As a full-fledged member of the EA, and the acquired status of an MLA signatory, the IARM shall have to pay an annual fee in the amount of 14,000.00 EUR, and as a full-fledged member of the ILAC with the MRA signatory status, the IARM shall be required to pay the annual fee of 1,500.00 USD.

Pursuant to the membership status, and in particular the MLA signatory status, the IARM 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 2013. 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).

As a full-fledged member of the ILAC world organization and a signatory of the ILAC-MRA, one representative of the IARM shall attend the annual ILAC General Assembly meeting in 2013.

As per the decision adopted on the sixth session of the Macedonian- Russian Intergovernmental Commission for Trade, Economic, Scientific and Technical Cooperation (July 2012), and the expressed interest by the Russian Accreditation for strengthening the cooperation in the area of accreditation between both states, the IARM submitted a draft-text on an Agreement for Cooperation with the national accreditation authority in Russia. This Agreement shall regulate the mutual cooperation in the area of accreditation, in order to facilitate trade and diminish trade barriers between both countries. The Agreement shall be signed during 2013.

At a regional level IARM has signed Bilateral Cooperation Agreements with the national accreditation authorities of Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo, Bosnia and Herzegovina and Moldova. The purpose of these Agreements is to organize

shared assessors training, exchange of experts and assessors on a regional level which will contribute towards designing an efficient accreditation system. Within the agreed regional cooperation, the launched activity of shared witnessing during assessment by the employees of the national accreditation authorities in the region shall continue.

Necessary funds 2,536,000.00 MKD

9. Management and current operation of the IARM

For the regular delivery of IARM's activities, the IARM Budget for 2013 shall allocate funds for maintenance of hardware and software equipment (software for accounting, treasury and filing), maintenance of the Training Center, maintenance of the passenger motor vehicle as well as procurement of computer equipment.

Since 2011, the IARM has implemented software for the delivery of accreditation procedures, and the public procurement was co-financed by the budget under the IPA-2008 project. As a result, the IARM in the forthcoming fiscal 2013 shall have an outstanding debt from 2011 for software payout payable to the supplier in the amount of 1,2 million MKD. Also, resources are planned for maintenance and upgrade of the implemented software (Data Management System).

Necessary funds..... 2,800,000.00 MKD

10. Inclusive of 31st January 2014, the IARM shall submit a report containing financial indicators for the implementation of the Work Program of the IARM for 2013, to the Government of the Republic of Macedonia encompassing the achieved outputs and financial indicators, as well as the elaboration of potential deviations from planned activity.

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

Number: 41-9681/1-12

Date: 03th January 2013

**Deputy President of the Government
of the Republic of Macedonia
Zoran Stavreski, M.Sc.**
