



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

**WORK PROGRAM
of the Institute for Accreditation
of the Republic of Macedonia for the year 2014**

Act: PR 2014

On the basis of Article 5, paragraph 2 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/09 and 53/11), the Government of the Republic of Macedonia on the session held on the 08th January 2014 adopted the following

Work Program of the Institute for Accreditation of the Republic of Macedonia for the year 2014

I. Introduction

The Law on Accreditation 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.

The accreditation is a formal recognition procedure that a particular body is qualified to fulfil certain activities, implying that a given accredited conformity assessment body meets the requirements stipulated by the national, European, and international standards, the particular legal regulations, IARM's procedures, as well as the requirements by the European and other global accreditation organizations. The core of accreditation is for the subject to apply in its activities particular standard/standards from the MKC EN ISO/IEC 17000 and MKC EN 45000 series.

Core fields to carry out the accreditation procedure are the following:

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

Accreditation represents an internationally recognized tool, which directly provides for the quality of products on one hand, and development of trade relations on an international level on the other. The core of accreditation is to strive towards greater quality and competitiveness of products and services at a reduced cost and errors in the working process, in order to increase the efficiency and economy in exploitation of both material and human resources, on a national and international level. Therefore the accreditation plays a pivotal role of catalyst in diminishing technical barriers and providing continuous trade exchange across the world, or simply put "Accreditation leads to facilitating global trade". The reason for this lies in its primary meaning or benefit that once the products and services have been examined/certified under the accreditation sign, there is not obligation to be re-examined when exported abroad where national accreditation body is a signatory of particular international agreements. We would like to emphasize here that IARM is a signatory of two significant agreements by which this benefit is obtained in the domestic economy.

Taking into consideration these benefits, the businessmen are more interested to benefit from accreditation through implementation of accreditation quality management systems.

Pursuant to the Law on Accreditation, the accreditation of one subject is carried out on their personal request, i.e. accreditation is not mandatory in the essence. Yet, bearing in mind its role as a regulators' and state tool, in certain fields accreditation it is stipulated as a legal provision which a certain subject is obligated to fulfil, in cases when this subject needs certain authorization issued by a competent state organ for its operations. From this aspect, accreditation is imposing as an essential working condition of particular subjects like the inspection bodies (to carry out inspection for pressure measuring equipment, of lifts, cranes, single approval of vehicles, tachographs, taximeters etc.), testing and calibration laboratories, medical laboratories, certified bodies for product certification (to carry out control and certification of organic agricultural production), of quality and personnel management systems.

The accreditation procedure is carried out at the request of domestic and foreign legal subjects, and it is based on the Law on Accreditation and other laws and in compliance with the requirements of the particular Macedonian, European and international standards and documents stipulated by the national, European and international organizations.

As of 2012, IARM is a signatory of two significant international agreements: Multilateral Agreement with the European cooperation for Accreditation – EA-MLA (Multilateral agreement – MLA¹) and with the International Laboratory Accreditation Cooperation ILAC-MRA (Multirecognitional agreement - MRA²), 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 product certification bodies shall be globally recognized.

Hereof, IARM shows a special interest and vision to maintain and strengthen the status of full-fledged member of the European cooperation for accreditation – EA and of the International Laboratory Accreditation Cooperation - ILAC. IARM continues its active participation in the working process of the European and international accreditation organizations and to represent Republic of Macedonia's interests within the afore stated.

In accordance with Article 14, paragraph 1 of the Law on Accreditation, 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 2014

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.

¹ MLA 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.

² MRA 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 the world.

Accreditation, both across the world and in Republic of Macedonia 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 consideration 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 subjects 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 subjects, 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 2014 shall be directed towards preparing for the first surveillance visit by the EA, which includes evaluation and expanding IARM's accreditation scope for medical laboratories, 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 March 2014.

Special objectives for the enforcement of the Program 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 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 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 2014 ("Official Gazette of the Republic of Macedonia" No 180/13), section 10001 – Ministry of Economy, in the subprogram 51 –

IARM, categories 42 – goods and services and 46 – subsidies and transfers and 48 - capital expenditure has planned funds in the amount of 14,030,000.00 MKD.

For the establishment and maintenance of an efficient national accreditation system in accordance with the Law on Accreditation, the standard MKS EN ISO/IEC 17011, as well as the rules of the European cooperation for Accreditation and the International Laboratory Accreditation Cooperation (EA and ILAC), the following activities need to be carried out:

1. Accreditation activities

IARM has so far accredited 131 conformity assessment bodies and has 30 new pending applications for accreditation. In 2014 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., as for instance the new schemes for accreditation of medical laboratories that has already been developed. The application of the new versions of the standards MKC EN ISO/IEC 17020 and MKC EN ISO/IEC 17065 will demand particular engagement. The development of these schemes shall be concurrent and in cooperation with the interested parties, supported by the work of the Technical Committees.

IARM's work priority in the course of 2014 will be implementation of the Government of Republic of Macedonia's projects, connected directly to the accreditation procedures.

Within the Project on Equipping Laboratories, of 80 tertiary education institutions, some 50 newly-formed laboratories are envisaged to be accredited. Preparation procedures for their accreditation have already commenced, thus IARM plays an active role in the creation of this project and determination of directions of its promotion. In compliance with the Action Plans of the Ministry of Education and Science, and the faculties separately, the applications for accreditation of laboratories are envisaged to be submitted including May 2014, whereas the accreditations shall be concluded including October 2014.

Additionally, IARM will respond to the requirement of the Ministry of Health on accreditation of 7 medical laboratories in Republic of Macedonia. Their accreditation shall be carried out in accordance with an already developed accreditation scheme for medical laboratories according to the standard MKC ISO 15189. The accreditation procedures for these laboratories are also envisioned to finish in October 2014.

Simultaneously, IARM will continue to process the current and upcoming applications for accreditation for medical laboratories, including the private sector as well, according to the same standard, which has aroused a great interest.

As another major activity in the course of the upcoming 2014 will be the implementation according to the regulations of the Law on Establishing a Quality Management System and a Multilateral Framework to Assess Work and Services in Public Administration ("Official Gazette of Republic of Macedonia" No 69/13), according to which the certification bodies that will certify the implementation of ISO 9001 in public institutions, are obligated to be accredited by IARM.

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 the 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.

This envisioned increased scope of accreditation activities will instigate as a supplementary element realization of particular trainings both for IARM's staff, out of which 10 employees are leading assessors, and for the rest of the external associates.

Necessary funds 6,530,000.00 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 from 10th to 14th March 2014. The surveillance visit takes place two years following the initial peer evaluation visit. 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). Nevertheless, the surveillance team members are assessors coming from the accreditation bodies in Holland, Ireland, Austria, England and Poland. The surveillance evaluation visit, at the same time will be used to expand the scope of the Accreditation Agreement for Medical Laboratories according to the standard MKC ISO 15189.

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 both a necessity, and a primary obligation for the IARM resulting from the international agreements. Hence, the forthcoming year shall also bear particular emphasis on organization of and participation in training, seminars and workshops.

Training of IARM's staff is of utmost importance in order to fulfil the planned accreditation activities as well, stipulated in Section III, Indent 1 from the Programme, i.e. this would lead to a more efficient and expert response to the requirements for the body accreditation.

In 2014, 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 and training by engaging them into the supervised assessments. Throughout this process, 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 resorted 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 2013, the List of Assessors was comprised of 18 leading assessors, 34 technical assessors, 14 assessors in training, 6 candidates for assessors and 40 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 2014, the IARM shall organize the following training:

- Training for staff 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 shall be mandatory, in order to maintain the accreditation system);
- 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 and/or workshops on specific technical requirement;
- Training on accreditation of medical laboratories on the standard MKC ISO 15189
- Training for assessors on new/revised standard MKC ISO 15189
- Training for development of new accreditations schemes for:
- Accreditation of bodies organizers of testing for qualification according to the standard MKC EN ISO/IEC 17043:2010
- Accreditation of products, processes and services certification bodies, according to the standard MKC EN ISO/IEC 17065:2012 and
- Accreditation of certification bodies personnel according to the standard MKC 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 400,000.00 MKD

4. Project: „Quality management systems in Republic of Macedonia – problems and solutions“

In the course of 2014, IARM in cooperation with competent institutions and experts in the field of quality management systems, will commence the delivery of the project: “Quality management systems in Republic of Macedonia – problems and solutions”.

The aim of this project is to assist the managements in maximum usage of the benefit from the quality management systems, concurrently to provide a higher quality level of products and services, reducing costs, errors and problems in the working process, increasing efficiency and economy of operations.

It is IARM's plan to carry out this initiative in cooperation with all relevant subjects in the Republic of Macedonia, in order to fulfil its core idea as a partner in the domestic economy, through its activities to provide a bigger competitiveness on the foreign markets. Undoubtedly, IARM's basic accreditation activity is decisive to ensure quality, not only through formal recognition of subjects' competency, yet of providing essential components of the latter, i.e. providing confidence in maintaining product and services quality.

Pursuant to the concept plans the Project is envisaged to be carried out within 36 months through team activities and particular scientific and research methodology.

The project's final product implies promotion of the results as well.

Necessary funds 300,000.00 MKD

5. 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.

6. 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 President 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.

7. Promoting the accreditation system

Pursuant to the continuous recommendations by the Government of the Republic of Macedonia, the IARM, 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 stated recommendations, greater familiarization as to both the manner of application and the method of obtaining accredited body status shall be required. IARM shall also organize new promotional events familiarizing all interested parties as to the benefits and advantage of signing the international agreements EA-MLA and ILAC-MRA and the usage of the signs confirming the signatory status of the stated.

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

- Preparation and issuance of promotional and educational material in the area of accreditation, on topics recommended by the European and global accreditation organization;
- Media promotion of accreditation with particular video materials;
- Issuance of an Annual Report on the work of IARM for 2013;
- Ceremony of awarding of certificates to accredited bodies in 2013/14. This promotional event shall take place on the 9th June, on the World Accreditation Day;

- Organization of press conferences;
- 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 meetings with businessmen in several towns throughout the territory of Republic of Macedonia;
- Protection of the logo and the accreditation sign in the Industrial Property Protection Office.

Necessary funds 700,000.00 MKD

8. 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

9. International activities

As a full-fledged member of both of the international organizations, the IARM is obligated to pay a certain amount in the form of annual fee for 2014.

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 3.000 AUD.

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 2014. Also, 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, there will be one representative of the IARM attending the annual ILAC General Assembly Meeting in 2014.

In compliance with the decision adopted by the Macedonian- Russian Intergovernmental Commission for Trade, Economic, Scientific and Technical Cooperation, the IARM have to sign an Agreement for Cooperation with the national accreditation body in Russia. This Agreement shall regulate the mutual cooperation in the area of accreditation, and according to the negotiation intensity, it is planned that the Agreement shall be signed in March 2014.

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 2,000,000.00 MKD

10. Management and current operation of the IARM

For the regular delivery of IARM's activities, the IARM Budget for 2014 shall allocate funds for maintenance of hardware and software equipment (software for accounting, treasury and filing), maintenance of the premises, maintenance of the passenger motor vehicle as well as procurement of computer equipment.

Resources are planned for maintenance and upgrade of the implemented software for the delivery of accreditation procedures (Data Management System) as well. The public procurement for the latter was co-financed by the budget under the IPA-2008 project.

Necessary funds..... 2,600,000.00 MKD

11. Inclusive of 31st January 2015, the IARM shall submit a report containing financial indicators for the implementation of the Work Program of the IARM for 2014, 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.

12. 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: 41-10554/1-13

Date: 08th January 2014

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