



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

**W O R K I N G P R O G R A M  
of the Institute for Accreditation  
of the Republic of Macedonia for 2015**

**Act: PR 2015**

On the basis of Article 5, paragraph 2 of the Law on Accreditation ("Official Gazette of the Republic of Macedonia", No.120/09, 53/11 and 41/14), the Government of the Republic of Macedonia on the session held on 21<sup>th</sup> of December 2014 adopted the following

## **Working Program of the Institute for Accreditation of the Republic of Macedonia for 2015**

### **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 single national accreditation body, as well as the procedure for accreditation pursuant to this and other laws and the supervision over the fulfillment of the requirements for accreditation.

The accreditation is a formal recognition procedure that a particular body is qualified to fulfill 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 precondition for accreditation is the applicant to have implemented in its activities particular standard/standards from the MKC EN ISO/IEC 17000 and MKC EN ISO 15189 series.

Core fields in which accreditation procedures are performed are the following:

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

Accreditation is an internationally recognized tool, which directly provides and guarantees safety and quality of products and services on one hand, and free development of international trade on the other. These are actually the benefits of accreditation, whose additional objective is reduction of costs and errors in the working process, in order to increase the efficiency and economy in exploitation of both material and human resources. Hence accreditation makes products and services more competitive on the market, both on national and international level. Therefore accreditation plays a pivotal role of catalyst in trade 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 no need for re-examination. Considering the fact that the IARM is a signatory of two significant international agreements by which this benefit is obtained, it applies to domestic products and services marketed in and out of the country. Thanks to these already obtained benefits, businessmen are more interested to use accredited services. Pursuant to the Law on Accreditation, accreditation of one subject is carried out on their personal request, i.e. generally, accreditation is not mandatory. Yet, bearing in mind its role as a regulators' and state tool, in certain fields accreditation is stipulated as a legal provision which a certain subject is obligated to fulfill, in cases when this subject needs certain authorization issued by a competent state body for its

operations. From this aspect, accreditation imposes itself as an essential working condition for particular subjects, such as the inspection bodies (e.g. for performing inspection of pressure measuring equipment, of lifts, cranes, single approval of vehicles, tachographs, taximeters etc.), testing and calibration laboratories, medical laboratories, product certification bodies (e.g. for performing control and certification of organic agricultural production), for quality management systems certification (e.g. certification of state and local government bodies and other state bodies).

The accreditation procedure is performed at 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 appropriate Macedonian, European and international standards and documents stipulated by national, European and international organizations.

In 2012, the IARM became a signatory of two significant international agreements for mutual recognition of accreditation certificates with the European cooperation for Accreditation - EA-MLA (Multilateral agreement – MLA<sup>1</sup>) and with the International Laboratory Accreditation Cooperation -MRA (Mutual Recognition Arrangement- MRA<sup>2</sup>). By signing them, the IARM opened the gates for the domestic products and services 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 MKC EN ISO/IEC 17025 for testing and calibration laboratories, MKC EN ISO/IEC 17020 for inspection bodies and the documents for product certification bodies shall be globally recognized. In this category, the documents issued by the domestic accredited medical laboratories shall be included after the formalization of the EA-MLA Agreement in this field.

Namely, during the preparation of this Program, the IARM obtained a certificate for meeting the requirements and conditions for expanding the scope significance of the EA-MLA Agreement with EA for acceptance/ recognition of the results of the accredited medical laboratories. This certificate and recommendation was given during the first regular supervisory assessment realized by the EA assessment team, which confirmed the consistency in maintaining and upgrading the IARM quality management system, i.e. confirming the validity and harmonization of the accreditation procedures performed by the IARM. At the same time, the work of the IARM in a new field- medical laboratories accreditation was confirmed as well.

Hereof, the IARM shows a strategic interest and vision to maintain and strengthen the status of a full-fledged member of the European cooperation for Accreditation – EA and of the International Laboratory Accreditation Cooperation – ILAC, as well as to apply for membership in the International Accreditation Forum – IAF. In this aspect, the IARM continues its active participation in the working process of the European and international accreditation organizations and represents the interests of the Republic of Macedonia in them.

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<sup>1</sup> MLA is an agreement signed between the EA accreditation body members to recognize the equivalence and reliability and therefore acceptance of accredited certification, inspection and calibration certificates and test reports across Europe.

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

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 Annual Working Program.

## **II. Aims of the Working Program of the IARM for 2014**

The primary aim of the IARM is continuous maintaining and strengthening of the accreditation system and so obtaining confidence in the competence of the conformity assessment bodies (certification bodies, testing and calibration laboratories, medical laboratories and inspection bodies) and in their issued documents concurrently facilitating free trade of domestic products and services to the European and global markets.

Accreditation, both across the world and in the Republic of Macedonia, plays a pivotal role in the strengthening of the internal markets and the quality of life and its role lays primarily in the development of the domestic economy and its global integration. Additionally, for the Republic of Macedonia, accreditation is an especially important instrument in the support of its integration 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 legislation with the European, 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 successful performance of the accreditation activity, as well as potentials arising from them, their multipurpose must be also considered. 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 upgrading, and on the other it 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 the work of the IARM, 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 foreign subjects, not residential to the Republic of Macedonia, and at locations in countries which are not signatories of these Agreements.

Therefore, the main activities of the IARM in 2015 shall be directed towards regular activities of maintaining and upgrading the quality management system as a prerequisite to maintain the Agreements and official signing of the EA-MLA Agreement with EA regarding the scope for medical laboratories in accordance with the rules, plans and working program of the European cooperation for Accreditation.

Special objectives for the enforcement of the Program are as follows:

- Increase in the number of accredited bodies by the IARM both in the Republic of Macedonia and abroad,
- Institutional strengthening by new personnel and organizational solutions and coordination of the accreditation activities by expanding the number of technical assessors and experts and professional development of the competencies of the assessors and the employees of the IARM;
- Continuous efforts invested in facilitation of global trade by accepting the results of the accredited conformity assessment bodies;
- Promotion of the services of the conformity assessment bodies accredited by the IARM;
- Implementation of Government projects related to the operation of the IARM;
- Working on a domain research project;
- 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 organizations;
- Application for membership in IAF,
- Continuous work for winning greater trust of the interested parties,
- Continuation of the established cooperation with the Economic Chambers of the Republic of Macedonia, the Consumers' Organization of Macedonia and the economic operators,
- Deepening and expanding the cooperation with the national accreditation bodies in the region and in the world and
- Participation in realization of international projects.

The realization of the aims of the program shall be provided by the Budget of the RM for 2015 as well as by participation in projects, such as the *Promotion of Regional Cooperation in South Eastern Europe in the Field of Quality Infrastructure* Regional Project (PTB) financed by the German Metrology Institute, the TAIEX Instrument of the European Commission etc.

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

The Budget of the Republic of Macedonia for 2015 ("Official Gazette of the Republic of Macedonia" No 155/14), 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 28.280.000 MKD.

For maintenance of the efficiency and upgrading of the established national accreditation system in accordance with the Law on Accreditation, the MKC EN ISO/IEC 17011 standard, as well as the rules of the European and international cooperation for accreditation (EA and ILAC) and the internal documents of the IARM, the following activities need to be carried out:

### **1. Accreditation activities**

So far, the IARM has accredited 146 conformity assessment bodies and has 30 new pending applications for accreditation. In 2015 regular surveillances over the already accredited bodies will be performed and at the same time, the IARM shall work on the newly submitted applications for accreditation which means increase in the number of accredited conformity assessment bodies.

In accordance with the 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 personnel and for organizers of qualification testing. The development of these schemes shall be in cooperation with the interested parties, supported by the work of the Technical Committees.

Priority in the work of the IARM in 2015 will be the implementation of the projects of the Government of the Republic of Macedonia connected directly to accreditation procedures.

The work on the project on accrediting laboratories within the Project on Equipping Laboratories, of 80 tertiary education institutions, some 50 newly-formed laboratories are envisaged to be accredited. The preparation procedures for their accreditation have already commenced and the applications for accreditation of laboratories are envisaged to be submitted to the IARM soon so that the accreditation procedures can be performed in the course of 2015.

Additionally, the same plan will be continued, i.e. the IARM will respond to the requirement of the Ministry of Health on accreditation of 8 medical laboratories in the Republic of Macedonia. Their accreditation shall be carried out in accordance with an already developed accreditation scheme for medical laboratories according to the MKC EN ISO 15189 standard. The accreditation procedures for these laboratories are also envisioned to be realized in the course of 2015.

Within these two projects, the IARM anticipates 30 new bodies to be accredited.

Simultaneously, the IARM will continue to process the current and upcoming applications for accreditation of medical laboratories, including the private sector as well, according to the same standard, for which a great interest is anticipated especially owing to the signing of the EA-MLA Agreement for this field as well.

The IARM will continue to participate in the implementation of the “Macedonian Sun” project of the Government of the Republic of Macedonia.

In 2015, a rise in the number of applications for accreditation of management system certification bodies is envisaged, 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 quality management systems according to ISO 9001 in public institutions are obligated to be accredited by the IARM.

Also, in 2015, accreditation activities abroad are envisaged within the cross border accreditation. Namely, according to the interest shown, applications for accreditation from the neighbouring countries (Bulgaria) are expected, where the IARM has already performed accreditation procedure of a conformity assessment body.

This envisioned increased scope of accreditation activities as a key element instigates a need for professional and adequate development via particular trainings both for IARM's staff, out of which 10 employees are leading assessors, and for the rest of the external associates.

## **2. Organization of training**

Maintaining and upgrading the competence of the staff of the IARM as well as of the external associates as an essential prerequisite for quality and correct performance of the accreditation activities and in order to expand the number of assessors used by the IARM for the accreditation procedures, is both a necessity and a primary obligation for the IARM resulting from the international agreements. Training of the IARM's staff is of utmost importance in order to fulfill the planned accreditation activities as well, stipulated in Section III, Indent 1 from the Program, i.e. this would lead to a more efficient and expert response to the requirements for the body accreditation. This way, conditions are provided to expand the Lists of assessors and experts with new persons, whose data are regularly updated.

In 2014, the List of Assessors was comprised of 19 leading assessors, 48 technical assessors, 11 assessors in training, 6 candidates for assessors and 60 experts. Ten of the leading assessors are employees 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 order to meet the requirements of the accreditation standards as well as to respond to the shown needs for accreditation, approximately 30% of the engaged technical assessors and experts in the implementation of the accreditation procedures are from abroad. However, the IARM will strive to increase the competence of the domestic assessors and experts by their training in order to increase their engagement in the accreditation procedures.

Hence, in 2015, particular emphasis shall be put on organization and participation in trainings, seminars and workshops with participation of the candidates for assessors and technical assessors and trainings by engaging them into supervised assessments.

In 2015, the IARM plans to organize the following trainings/ workshops:

- Training for the staff on the MKC EN ISO/IEC 17011 Standard - 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);
- Trainings for leading assessors on the following standards: MKC EN ISO/IEC 17025 for testing and calibration laboratories and MKC EN ISO/IEC 17020 for inspection bodies;

- Trainings for assessors on new/revised standards: MKC EN ISO/IEC 17065 and MKC EN ISO/IEC 17024 for certification bodies, MKC EN ISO/IEC 17020 for inspection bodies;
- Trainings for requirements for accreditation of medical laboratories according to the MKC EN ISO 15189 standard;
- Training for assessors on the new revised MKC ISO 15189 standard
- Training for assessors on the revised ISO/IEC 17021-1:2015 Standard
- Trainings on harmonization in assessing performed by leading and technical assessors of the IARM;
- Trainings for development of new accreditations schemes:
- Accreditation of PT providers according to the MKC EN ISO/IEC 17043:2010 standard and
- Accreditation of personnel certification bodies according to the MKC EN ISO/IEC 17024 standard, as well as
- Workshop on the following topic: "EU Legislation and Accreditation of Laboratories for Official Food Control".

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, some in the international accreditation bodies, members of EA and signatories of the MLA.

### **3. Project: "Quality management systems in the Republic of Macedonia – problems and solutions"**

In the course of 2015, the IARM will continue working on the project: "Quality management systems in the 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, to provide a higher level of confidence in the working of the subjects, reducing costs, errors and problems in the working process, increasing efficiency and economy of operations, motivating and engaging the employees and assisting them to meet the needs and requests of the clients.

The IARM carries out this initiative in cooperation with all relevant subjects in the Republic of Macedonia, competent institutions and experts in the field of quality management systems in order to fulfill its core idea as a partner in the domestic economy, through its activities to provide for it greater competitiveness on the foreign markets as well as to place it on new markets. Undoubtedly, IARM's basic accreditation activity is decisive to ensure confidence in the competence of the certification bodies certifying quality systems contributing to provide confidence in the subjects'



operations. The Project realization is based on team activities and appropriate scientific and research methodology.

#### **4. Performing internal audit**

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

#### **5. Management review**

In accordance with the Quality Policy and Work Procedures of the IARM and the requirements of the MKC EN ISO/IEC 17011, 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 Sections) 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 recommendations by the Government of the Republic of Macedonia, the IARM shall undertake activities in favor of greater 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 projects of the Government of the Republic of Macedonia: "Macedonian Sun" foreseeing all Macedonian products to be analyzed by the laboratories accredited by the IARM, the project of the Ministry of Education and Science for accreditation of laboratories of the tertiary education institutions and the project of the Ministry of Health for accreditation of medical laboratories.

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. The 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 afore 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
- Issuance of an Annual Report on the Work of IARM for 2014;
- Ceremony of certificate awarding to the accredited bodies in 2014/15. 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 meetings with the Economic Chambers of the Republic of Macedonia;
- Organization of meetings with businessmen in several towns throughout the territory of Republic of Macedonia;
- Maintenance and upgrading of the official website of the IARM.

## **7. Work of the IARM Council and the Material and Financial Supervision Board of the IARM**

The IARM Council is composed of 11 members and the Material and Financial Supervision Board of 3 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 year.

## **8. International activities**

The IARM is a full-fledged member of the European cooperation for Accreditation (EA) and of the International Laboratory Accreditation Cooperation (ILAC).

As a full-fledged member of both of the organizations, the IARM shall mandatorily participate in the annual meetings of the General Assemblies of EA and ILAC since it is a member with an active right and obligation to participate and vote for new measures and resolutions in the field of accreditation globally which it should later transcribe vertically in an appropriate legal form on a national level.

As a full-fledged member, the IARM is obligated to pay a certain amount in the form of annual membership fee for 2015 as follows:

- as a full-fledged member of the EA and with the acquired status of an MLA signatory, the IARM shall have to pay an annual membership fee in the amount of 14.000 EUR,
- as a full-fledged member of the ILAC with the MRA signatory status, the IARM shall be obliged to pay the annual membership fee of 3.000 AUD.

In 2015, the IARM will file an application for membership in the International Accreditation Forum (IAF) which is envisaged as a measure in the NPAA.

The IARM will maintain and upgrade its cooperation with the national accreditation bodies in the region pursuant to the signed Bilateral Agreements with: Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo, Bosnia and Herzegovina and Moldova.

Also, the IARM will maintain and upgrade the cooperation agreements concluded with the United Kingdom Accreditation Service (UKAS) and Germany's National Accreditation Body (DAKks).

On the basis of the signed Memorandum of Cooperation between the IARM and the Federal Accreditation Service of the Russian Federation (RusAccreditation), the cooperation between the two bodies shall be carried out according to the Annual Activity Program which will be prepared jointly.

The purpose of these Agreements is to organize shared assessors training, exchange of experts and assessors on a regional level, cross border accreditation which will in total contribute towards designing an efficient accreditation system. Within the agreed regional cooperation, the launched activity of shared participation in witnessing during assessment by the national accreditation authorities in the region shall continue.

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

For regular delivery of the activities of the IARM, the IARM Budget for 2015 shall allocate funds for maintenance of the 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.

#### **IV. Final provisions**

1. Inclusive of 31.03.2016, the IARM shall submit a Report containing financial indicators for the implementation of the Work Program of the IARM for 2015 to the Government of the Republic of Macedonia encompassing the achieved outputs and financial indicators, as well as the elaboration of potential deviations from the planned activities.

2. 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:**42-9832/1

**Date:**21<sup>th</sup> of December 2014

**President of  
the Government of the Republic of Macedonia,  
Nikola Gruevski, M.Sc**