



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

**WORKING PROGRAM  
of the Institute for Accreditation  
of the Republic of Macedonia for the year 2017**

**Act: PR 2017**

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, 41/14 and 53/16), the Government of the Republic of Macedonia on the session held on the 17<sup>th</sup> October 2016 adopted the following

## **Working Program of the Institute for Accreditation of the Republic of Macedonia for the year 2017**

### **I. Introduction**

According to the Law on Accreditation, the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM), is a public institution performing activities and tasks as a solely national accreditation body, in compliance with the procedure for accreditation pursuant to this and other laws and supervising 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. Given its role as a tool to regulators and the state, in certain areas accreditation is prescribed as a legal requirement that an entity must meet, if it should acquire for its work a specific authorization issued by competent authority.

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

- Testing and calibration laboratories,
- Medical laboratories,
- Certification bodies for products, processes and services,
- Management system certification bodies and
- Inspection bodies

Accreditation represents an internationally recognized tool, which directly provides and guarantees: safety and quality of products and services, free development of the international trade relations, decreasing costs and errors in operation, in order to increase the efficiency and economy in exploitation of both material and human resources.

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. Having in consideration that IARM is a signatory of three significant agreements by which this benefit is obtained, it is equally applicable to domestic products and services that are ranked home and abroad.

Namely, the IARM as a full-fledged member of the European and World Organizations for Accreditation is a signatory of the following Multilateral Recognition Agreement of the Certificates for Accreditation:

- With the European Cooperation for Accreditation (EA) signed the EA-MLA (Multilateral agreement – MLA<sup>1</sup>);
- With the International Laboratory Accreditation Cooperation (ILAC) signed the ILAC-MRA (Mutual Recognition Arrangement- MRA<sup>2</sup>) and

- With the International Accreditation Forum (IAF) signed the IAF-MLA Multilateral agreement – MLA<sup>3</sup>).

By signing these Agreements, the IARM opened the gates to the European and global 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, MKC EN ISO 15189 for medical laboratories and MKC EN ISO/IEC 17065 for certification bodies for products, processes and services shall be globally recognized.

The current implementation of the IARM's key commitments internationally, are only additional incentive and obligation for fulfilling the strategic interest and vision of IARM, towards maintaining and strengthening the status of full-fledged member of the international accreditation organizations.

## **II. Aims of the Work Program of the IARM for 2017**

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

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 the Republic of Macedonia, accreditation is an important instrument in the support of its approximation to the European Union.

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.

Hence, the main target of the activities of the IARM in 2017 will be maintenance and upgrading the system for quality maintenance, as an essential condition for supporting the contracts. These will be complemented by activities and preparations for the second regular oversight by EA following the signing of the EA-MLA Agreement. According to the rules, plans and work program of the European Cooperation for Accreditation, the second regular surveillance should be carried out in December 2017.

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<sup>1</sup> EA-MLA represents an agreement signed among the accreditation bodies, members of EA, for equivalence and reliability and therefore recognition of the accredited certifications, inspections and calibration certificates and test reports across Europe.

<sup>2</sup> ILAC-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.

<sup>3</sup> IAF-MLA represents an agreement signed among the accreditation bodies, members of IAF, to recognize the equivalence, reliability and therefore acceptance of the accredited certificates issued by the accredited certification bodies for products across the world.

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

- Increase in the number of accredited bodies by the IARM;
- Institutional strengthening of new staff and organizational solutions and coordination of the accreditation activities by expanding the number of technical assessors and experts and upgrading the competencies of the assessors and the employees in the IARM;
- Continuous efforts invested in facilitation of global trade by accepting the results of the accredited conformity assessment bodies;
- Promotion of services of 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 organizations for accreditation;
- Continuous activities for winning greater confidence among 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 national accreditation bodies' cooperation in the region and the world
- Participation in realization of international projects.

The realization of the program goals will be achieved by means of the Budget of the Republic of Macedonia for 2017, and also through participation in projects such as: The Project for strengthening the infrastructure quality facilities for the Western Balkans, TAIEX Instrument of the European Commission etc.

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

The Budget of the Republic of Macedonia for 2017, section 10001 – The Ministry of Economy, in the subprogram 51 – IARM, for categories 42 – goods and services and 46 – subsidies and transfers and 48 - capital expenditure, has planned funds in the amount of 30.780.000, 00 MKD.

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

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

The IARM has so far accredited 194 conformity assessment bodies and has 17 new applications in process for accreditation. In 2017 a regular surveillance over the accredited bodies will be carried out and the IARM shall also work on the new applications for accreditation which implies an 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 and areas pursuant to the specific needs of the Republic of Macedonia, such as: accreditation of certification bodies for personnel and proficiency testing providers. The development of these schemes and areas shall be in cooperation with the interested parties, supported by the work of the Technical Committees.

The IARM's work priority in the course of 2017 will be further implementation of the Projects of the Government of the Republic of Macedonia, connected directly to the accreditation procedures.

Namely, the IARM will continue the work on the project of laboratories' accreditation within the "Project for laboratory equipment of 80 state higher education institutions", by which accrediting of around 50 new formed laboratories is envisioned.

Also, the implementation of the accreditation procedures of the planned 8 medical laboratories in public health will be continued, in cooperation with the Ministry of Health. Simultaneously, the IARM will be processing the current and upcoming applications for accreditation of medical laboratories in the private sector too, according to the standard MKC EN ISO 15189.

In the course of 2017, a raise in the number of applications for accreditation of certification bodies for management systems is expected, and for that area the IARM will expand the scope of the EA-MLA agreement during the second regular surveillance by the EA.

Also, during 2017, the activities to perform the accreditation activities abroad will continue, respecting the rules on cross-border accreditation.

## **2. Second regular evaluation following the signing of the mutual recognition agreement of the accreditation certificates with the European Cooperation for Accreditation (EA-MLA)**

According to the rules, plans and work program of the European Cooperation for Accreditation (EA), the second regular evaluation after signing the agreement on mutual recognition of certificates of accreditation with the European Cooperation for Accreditation (EA-MLA) should be implemented in December 2017.

The evaluation will also include assessment of the accreditation system for a new field - certification of management systems, and will be implemented by the eight-membered international team delegated by EA. The overall organization and realization costs of evaluation borne by the IARM (travel costs, food and accommodation).

Keeping the importance of the agreement coupled with the expansion of its scope in a new field, through presentation and maintenance of the established system of accreditation and meeting the obligations arising from it through various activities is essential for the working of the IARM, for the Macedonian economy and country.

### 3. Organization of training

Maintaining and upgrading the competence of the staff of the IARM as well as of the external associates for the accreditation procedures, is both a necessity and a primary obligation for the IARM that results from the international agreements because it is a main condition for quality and proper performance of the accreditation.

In the course of program preparation the List of Assessors is comprised of: 20 leading assessors, 50 technical assessors, 10 assessors in training, 8 candidates for assessors and 71 experts. Ten of the leading assessors are employees in the IARM, whereas the rest are external associates. The lists, aside from assessors and experts from RM, also contain assessors and experts from other accreditation bodies, members in the EA or those having signed cooperation agreements with the IARM. Namely, in order to fulfill the expectations of the accreditation standards, 18 % of the technical assessors and experts engaged in the implementation of the accreditation procedures are from abroad. However, IARM shall strive towards more intense engagement and competence improvement of domestic assessors and experts by trainings for the purposes of implementation of the accreditation procedures.

Therefore, in 2017, a particular emphasis will be put on organization and participation in trainings, seminars and workshops by participation of the assessors candidates and technical assessors and also trainings including assessments under surveillance.

In 2017, the IARM is planning to organize the following trainings/workshops:

- Training for staff on the standard MKC 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 on accreditation of medical laboratories on the standard ISO 15189:2012;
- Training for Point-of-care testing (POCT), Requirements of quality and competence (ISO 22870:2006);
- On-site assessment of stationary emission sources laboratories in accordance with CEN/TS 15675;
- Training on harmonization in the assessment of the leading and technical assessors of the IARM.
- Training for the leading and technical assessors on the standard MKC EN ISO/IEC 17020:2012;
- Training for the leading and technical assessors on the standard MKC EN ISO/IEC 17065;
- Training for assessors - on site assessment on MKC EN ISO/IEC 17025 in laboratories for microbiological food testing;
- Training for assessors - on site assessment on the standard MKC EN ISO/IEC 17021;
- Training on the standard MKC EN ISO/IEC 9001:2015;
- Training on the standard MKC EN ISO/IEC 14001:2015 and
- Training for Protected Designation of Origin, Protected Geographical Indication, Guaranteed Traditional Specialty.

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

Also, during the Annual Training Plan for the staff of the IARM, generic and specialized trainings will be realized, according to the legal requirements for professional upgrade and competence of the administrative workers.

#### **4. Cooperation with the state authorities**

The IARM will continue its active cooperation with state institutions through participation in the work of several working groups established by the Government of the Republic of Macedonia; the Ministry of Economy, the Ministry of Environment and Physical Planning and the Ministry of Agriculture, Forestry and Water Management.

In this direction will be continued the ongoing government projects on accreditation, the remaining laboratories accreditation in higher education institutions equipped by the Government of the Republic of Macedonia and accreditation of medical laboratories designated by the Ministry of Health.

Also, the IARM will continue its activities within the committee on market surveillance and cooperation with chambers of commerce in the country, as well as participating in the work of technical committees within the Standardization Institute of the Republic of Macedonia.

#### **5. Performing internal audit**

According to the requirements of the Standard MKC EN ISO/IEC 17011, the performance of the regular internal audit of the IARM's employees is a compulsory task and a necessity for maintenance and upgrade of the quality management system in the IARM.

#### **6. Management review**

In accordance with the Quality Policy and Work Procedures of the IARM and the requirements of the standard 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 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 of the accreditation system**

Pursuant to the recommendations by the Government of the Republic of Macedonia, the IARM is heading to 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 above mentioned Government projects.

For the purposes of full enforcement of the stated recommendations, information of the manner of application is necessary, as well as of the method of obtaining accredited body status, i.e. approximation to terms of accreditation. 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, ILAC-MRA and IAF-MLA 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;
- Issuance of an Annual Report on the work of IARM for 2016;
- Ceremony of awarding of certificates to accredited bodies in 2016/17. 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 and participation in the Third International Conference,, Quality and competency 2017 "in cooperation with the Macedonian Association of accredited laboratories and inspection bodies - MAKLAB,
- Organization of meetings with businessmen in several towns throughout the territory of Republic of Macedonia;
- Maintenance and upgrading of the official internet site of the IARM.

## **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 the IARM is composed of 3 members.

## **9. International activities**

The IARM is a full-fledged member of the European Organization for Accreditation (EA), the International (World) organization for laboratory accreditation (ILAC) and the International Accreditation Forum (IAF).

As a full-fledged member of these three organizations, the IARM is obliged to participate on the annual meetings of the General Assembly of EA, ILAC and IAF, because it is a member with active right and responsibility to participate in and vote for new measures and resolutions in the accreditation area worldwide, which then should be transposed vertically on a national level in an appropriate legal frame.

As a full-fledged member, the IARM shall have to pay an annual fee for 2017 as follows:

- 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;
- 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;



-as a full-fledged member of the IAF and the acquired status of an MLA signatory, the IARM shall have to pay an annual fee in the amount of 1.306 USD.

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

Also, the IARM shall maintain and upgrade the Cooperation Agreement signed with the Accreditation Service of Great Britain (UKAS) and the German Accreditation body (DAkkS) as well as with the Federal Service for Accreditation of the Russian Federation (RusAccreditation).

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.

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

For the regular delivery of IARM's activities, the IARM Budget for 2017 shall allocate funds for maintenance of hardware and software equipment (software for implementation of the accreditation procedures (Data management system), software for accounting, treasury and filing), maintenance of the premises, maintenance of the passenger motor vehicles as well as procurement of computer equipment.

#### **IV. Final Regulations**

1. Inclusive of 31st March, 2018, the IARM shall submit a report containing financial indicators for the implementation of the Work Program of the IARM for 2017, 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.

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" and will be valid from 01.01.2017 year.

**No:42-7720/1**

**Date: 17<sup>th</sup> October 2016**

**Deputy President of the Government  
of the Republic of Macedonia,  
Nikola Todorov**