



**INSTITUTE FOR ACCREDITATION OF REPUBLIC
OF MACEDONIA**

**WORKING PROGRAM of the Institute for
Accreditation of the Republic of Macedonia for the
year 2018**

Act: PR 2018

Pursuant to 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 Republic of Macedonia, on the session held on the 30th of January 2018 adopted the following

Working Program of the Institute for Accreditation of the Republic of Macedonia for the year 2018

I. Introduction

According to the Law on Accreditation, the Institute for Accreditation of Republic of Macedonia (hereinafter: IARM) is a public institution performing activities and tasks as the solely national accreditation body, in compliance with the procedure for accreditation pursuant to this and other laws, and supervising the fulfilment 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. Having in mind its role as an instrument of the 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 operations a specific authorization issued by a competent authority.

Main areas, where accreditation procedures are being implemented, are as follows:

- 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 instrument, which indirectly provides and guarantees: the safety and quality of products and services, free development of international trade relations, decreases costs and errors in operation, for the purpose of increasing the efficiency and cost-effectiveness in exploitation of both material and human resources.

Accreditation provides global trade facilitation. 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 mind that IARM is signatory of three significant international agreements that ensure this benefit, it is equally pertinent to domestic products and services that are placed on domestic and foreign markets.

Namely, IARM, as a full member of the European and global organizations for accreditation, is a signatory of the following Multilateral Recognition Agreement of the Certificates for Accreditation, as follows:

- with the European Cooperation for Accreditation (EA), signatory of the EA-MLA (Multilateral agreement – MLA¹);
 - with the International Laboratory Accreditation Cooperation (ILAC), signatory of the ILAC-MRA (Mutual Recognition Arrangement - MRA²), and
- with the International Accreditation Forum (IAF), signatory of IAF-MLA Multilateral Agreement MLA³) on accepting accredited certificates issued by accredited certification bodies for global products.

By signing these Agreements, IARM opened the doors of the European and global markets for domestic products, following the principle “accredited once, accepted everywhere”.

The signing of the agreements means that the documents issued by 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, are globally recognized.

The current implementation of IARM’s key international commitments is an additional incentive and an obligation for fulfilling the strategic interests and visions of IARM towards maintaining and strengthening the status of full member of the international accreditation organizations.

II. Objectives of the 2018 IARM Working Program

Primary objective of the IARM is to continuously maintain and strengthen the accreditation system, thus ensuring confidence in the competence of the conformity assessment bodies (certification bodies, testing and calibration laboratories, medical laboratories, and inspection bodies) and the documents issued thereby, 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 an important role in strengthening internal markets and quality of life, whereas its primary role is developing the domestic economy and integrating it globally. However, for Republic of Macedonia, accreditation is an important instrument supporting its accession to the European Union.

Taking into consideration the benefits from implementing the previously set out plans and objectives of IARM, acknowledging its successful performance of the accreditation activity, as well as the potential arising thereof, one must also consider their multi-faceted purpose.

Hence, the main activities of IARM in 2018 will be aimed at the regular activities for maintaining and upgrading the quality management system, as an essential pre-requisite for maintain the agreements. These will be supplemented by activities for verification of the Report on the second regular surveillance by EA, following the signing of the EA-MLA Agreement. According to the rules, plans and operating program of the European Cooperation for Accreditation, the second regular surveillance took place in the period 13-17 November of 2017.

Special objectives for enforcement of the Program are as follows:

- Increase in the number of bodies accredited by IARM,

1 EA-MLA represents an agreement signed among accreditation bodies, members of EA, for equivalence and reliability and therefore recognition of the accredited certification, inspection and calibration certificates and test reports across Europe.

2 ILAC-MRA is an agreement signed between accreditation body, ILAC members, to recognize the equivalence and reliability, and therefore accept the accredited inspection and calibration certificates and test reports across the world.

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

- Institutional strengthening of new staff and organizational solutions and coordination of the accreditation activities by expanding the number of technical assessors and experts, and by upgrading the competencies of the assessors and employees in the IARM,
- Continuous efforts in facilitation of global trade by accepting the results of accredited conformity assessment bodies,
- Promotion of services of conformity assessment bodies accredited by IARM,

- Provision of technical support to ministries and other institutions on all issues related to accreditation procedures,
- Active cooperation with European and international organizations for accreditation,
- Continuous activities for attaining greater confidence among the concerned parties,
- Continuation of the established cooperation with Economic Chambers in Republic of Macedonia, the Consumers' Organization of Macedonia, and economic operators,
- Deepening and expanding the national accreditation bodies' cooperation in the region and the world, and
- Participation in international projects.

The fulfilment of the Programme objectives will be ensured through the funds provided in the 2018 Budget of RM, as well as through participation in projects, such as: Project for strengthening the infrastructure capacities for quality for the countries of the Western Balkans, the TAIEX Instrument of the European Commission, and others.

Envisaged activities for Program implementation The 2018 Budget of Republic of Macedonia, Section 10001 – Ministry of Economy, Sub-programme 51 – IARM, for categories 42 – goods and services, 46 – subsidies and transfers, and 48 – capital expenditure, has envisaged funding of MKD 30.780.000,00.

For the purpose of maintaining efficiency and upgrading the established national accreditation system, as per the Law on Accreditation, Standard MKC EN ISO/IEC 17011, the rules of the European Cooperation for Accreditation, the International Laboratory Accreditation Cooperation, and the International Accreditation Forum (EA, ILAC и IAF), and the internal documents of IARM, the following activities have to be completed:

1. Accreditation activities

IARM has so far accredited 209 conformity assessment bodies and has 17 new applications for accreditation. In 2018, regular surveillance over the current accredited bodies will be carried out, and at the same time IARM will also work on the new accreditation applications, which implies an increase in the number of accredited conformity assessment bodies.

In accordance with the Law on Accreditation and the obligations arising from the signed international agreements, IARM will continuously maintain and improve the overall accreditation system. Within the activities for development, IARM will develop new accreditation schemes and accreditation areas, pursuant to the specific needs of Republic of Macedonia, such as: accreditation of certification bodies for personnel and proficiency testing providers. The development of these schemes and areas will be in cooperation with concerned parties, supported by the work of the Technical Committees.

In the course of 2018, a raise in the number of applications for accreditation of certification bodies for management systems is expected, and for that area the IARM expanded the scope of the EA-MLA agreement during the second regular surveillance by the EA.

Also, during 2018, accreditation activities abroad will also continue, observing the rules on cross-border accreditation.

Required funding.....20.900.000,00 denars

2. Verification of the Report on the 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 operating program of the European Cooperation for Accreditation (EA), the second regular surveillance, following the signing of the Multilateral Agreement with the European Cooperation for Accreditation (EA-MLA), took place between the 13th and 17th of November, carried out by an EA assessment team comprising 9 members.

The surveillance assessment included assessment of the accreditation system for a new area – management system certification. In the upcoming period, as at April 2018, there will be joint activities of IARM and the EA working groups on verification of the Surveillance Report.

Maintaining the importance of the Agreement, supplemented with the scope expansion in a new area, by presenting and defending the established accreditation system, and by meeting the obligations arising thereof through various activities, are essential for IARM's activity for the Macedonian economy and the state.

Required funding..... 200.000,00 denars

3. Organisation 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.

At the time of the Program preparation, the List of assessors and experts - active consists of: 19 lead assessors, 63 technical assessors, 9 assessors in training, and 36 experts. Ten of the lead assessors are employees in the IARM, whereas the rest are external associates. The lists, aside from assessors and experts from Republic of Macedonia, also contain assessors and experts from other accreditation bodies, EA members or those that have signed cooperation agreements with IARM. Namely, in order to fulfil the requirements of the accreditation standards and to respond to the newly needed accreditation, about 18% of the technical assessors and experts engaged in implementation of the accreditation procedures are from abroad. Nevertheless, IARM will continue striving to increase the number of competent domestic assessors and experts, thus increasing their engagement in the accreditation procedures.

Accordingly, particular emphasis will be put in 2018 on organising and participating in trainings, seminars and workshops of assessor candidates and technical assessors, as well as trainings during surveillance assessments.

In 2018, IARM plans to organize the following trainings/workshops:

- Training for its staff and IARM's Council member on the new edition of the standard MKC EN ISO/IEC 17011 - General requirements for accreditation bodies accrediting conformity assessment bodies, standard adhered to by IARM (mandatory, in order to maintain the accreditation system);
- Training on accreditation of medical laboratories as per the standard ISO 15189:2012;
- Point-of-care testing (POCT) training, quality and competence requirements (ISO 22870:2006);
- On-site assessment of laboratories testing stationary emission sources as per TS EN 15675;
- Training on assessment harmonisation of lead and technical assessors within IARM;
- Training for lead and technical assessors on the standard MKC EN ISO/IEC 17020:2012;

- Training for lead and technical assessors on the standard MKC EN ISO/IEC 17065;
- Training for assessors - on site assessment as per the MKC EN ISO/IEC 17025 in laboratories for microbiological food testing;
- Training for assessors - on site assessment as per the standard MKC EN ISO/IEC 17021;
- Training on the standard MKC EN ISO/IEC 14001:2015;
- Training for Protected Designation of Origin, Protected Geographical Indication, Guaranteed Traditional Specialty;
- Training on ISO 9001:2015 and IAF MD documents;
- Training for evaluators in the field of organic production (incl. all of its specifics), in particular organic production in third countries;
- Training for the new standard ISO/IEC 17025:2017;
- Training for assessors on applying the ILAC-P14 document, and training on the manner of expressing the scope in the accreditation application, the attachment to the certificate and other documents;
- Trainings on the requirements of the standard 17021-1, and the use of IAF-MD documents pertaining to the standard;
- Development of sector schemes in accordance with EA-1/22, EA Policy for Conformity Assessment Schemes (Sector Schemes).

The trainings will be organized according to the identified needs and the current transitional periods of the international standards, and will be attended by the employees of IARM and other concerned parties, assessors, and experts.

Part of the theoretical trainings will be organized within IARM, and part within foreign accreditation bodies, EA members and MLA signatories.

Also, as part of the Annual Training Plan for the IARM's staff, generic and specialized trainings will be carried out, as per the legal requirements for professional and competence upgrade of administrative officers.

Required funding.....1.500.000,00 denars

4. Cooperation with state authorities

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

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

Required funding..... 100.000,00 denars

5. Internal Audit

According to the requirements of the Standard MKC EN ISO/IEC 17011, performing regular internal audit of IARM's employees is a compulsory task and necessary for the purpose of maintaining and enhancing the quality management system within IARM.

6. Management Review

In accordance with the Quality Policy and Work Procedures of IARM, and the requirements of the standard MKC EN ISO/IEC 17011, once a year, management review of IARM is performed (the Director, the President of the Council, the Quality Manager, Heads of Departments and Units). The purpose of the management review is to define and redefine the policies and aims of IARM, and to examine the efficiency of IARM's quality system through analysis of documents, reports, complaints, appeals, remarks and non-conformities.

7. Promotion of the accreditation system

IARM constantly strives to promote the need of accredited and authorized bodies with head offices in Republic of Macedonia. The promotion of the accreditation system shall be pivotal to the implementation of the above mentioned governmental projects.

In order to fully enforce these recommendations, information on application submission is necessary, as well as on the method of obtaining accredited body status, that is to say, familiarisation with the terms of accreditation. Also, IARM will organize new promotional events where all stakeholders will be introduced to the benefits and usefulness of signing the international agreements - EA-MLA, ILAC-MRA, IAF-MLA - and the use of marks proving their signatory status.

Within the promotional activities of the accreditation system, IARM will 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 organizations,
- Promotion of accreditation within the media,
- Issuance of the 2017 Annual Report on the IARM's Operation,
- Promotion of the certificates awarding to accredited bodies in 2017/18 on June 9th - World Accreditation Day and 15th Jubilee from the establishment of IARM,
- Organisation of press conferences,
- Organisation of joint events with the Consumers' Organization of Republic of Macedonia,
- Organisation of meetings with the economic chambers of Republic of Macedonia,
- Organisation of meetings with businessmen in several towns throughout the territory of Republic of Macedonia, and
- Maintenance and upgrading of the official web-site of IARM.

Required funding.....1.620.000,00 denars

8. The work of the IARM Council and the Material and Financial Control Supervision Board

IARM's Council is composed of 11 members, whereas the Material and Financial Control Supervision Board is composed of 3 members.

Required funding..... 1.700.000,00 denars

9. International activities

IARM is a full member of: European Cooperation for Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC), and the International Accreditation Forum (IAF).

As a full member of all three organizations, IARM is obliged to participate on the annual meetings of the General Assemblies of EA, ILAC and IAF, since it is a member with active right and responsibility to participate in and vote for the new measures and resolutions in the field of accreditation worldwide, which should then be transposed vertically on national level in the appropriate legal form.

Being a full member, IARM has to pay annual membership fees, which for 2018 are as follows:

- - as full member of EA, and for the acquired MLA signatory status, IARM has to pay an annual membership fee of EUR 10.907,00,
- - as full member of ILAC, and for the acquired MRA signatory status, IARM has to pay an annual membership fee of AUD 3.000,00,
- - as full member of IAF, and the acquired MLA signatory status, IARM has to pay an annual membership fee of USD 1.518,00.

IARM will maintain and enhance its cooperation with the national accreditation bodies in the region in accordance with the signed bilateral agreements with: Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo, Bosnia and Herzegovina, and Moldova.

Also, IARM shall maintain and upgrade the Cooperation Agreement signed with the United Kingdom Accreditation Service (UKAS), the German Accreditation Body (DAkkS), and the Federal Accreditation Service of the Russian Federation (RusAccreditation).

The purpose of these agreements is to organize joint assessors training, exchange experts and assessors on regional level, and cross-border accreditation, which will contribute towards an overall efficient accreditation system. Within the agreed upon regional cooperation, the activity of shared witnessing during assessment by national accreditation authorities in the region will continue.

Required funding.....2.800.000,00 denars

10. Management and current operation of IARM

For the regular delivery of IARM's activities, IARM's Budget for 2018 allocates funding for maintenance of the hardware and software equipment (software for implementation of accreditation procedures (data management system), software for accounting, treasury and archives operations), maintenance of premises, maintenance of passenger motor vehicles, as well as procurement of information and communication equipment.

Required funding.....1.960.000,00 denars

IV. Final Regulations

1. As at 31.03.2019, IARM shall submit a Report containing the financial indicators for implementation of the 2018 IARM Working Program to the Government of Republic of Macedonia, including also the achieved outputs and financial indicators, as well as elaboration on the 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 Republic of Macedonia”.

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Date: 30.01.2018

**President of
the Government of Republic of Macedonia
Zoran Zaev**