



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

**WORKING PROGRAM
of the Institute for Accreditation
of the Republic of Macedonia for the year 2019**

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, 53/16 and 83/18), the Government of Republic of Macedonia, on the session held on the 22th of January 2019 adopted the following

Working Program of the Institute for Accreditation of the Republic of Macedonia for the year 2019

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 the 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 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. 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 co-operation for Accreditation (EA), signatory of the EA-MLA (Multilateral agreement – MLA¹);

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

- 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 and reports issued by accredited conformity assessment bodies in the world.

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, and MKC EN ISO/IEC 17021-1 for certification bodies for management systems are recognized at European level, as well as globally.

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

II. Objectives of the 2019 IARM Working Program

Primary objective of 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 the Republic of Macedonia, plays an important role in strengthening internal markets, quality of life and safety, 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 integration 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 2019 will be aimed at the regular activities for maintaining and upgrading the quality management system, as an essential pre-requisite for maintaining the agreements.

- Primary objective for realization of the Programme:

During 2019, the attention will be focused on the full revision and compliance of IARM’s quality management system pursuant to the requirements of the new edition of the standard MKC EN ISO/IEC 17011:2018, as a basic and only standard by which IARM operates and carries out accreditation procedures.

² ILAC-MRA represents an agreement signed among accreditation bodies, ILAC members, for recognition of the equivalence and reliability, and therefore acceptance of 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, for recognition of the equivalence and reliability, and therefore acceptance of the accredited certificates issued by accredited certification bodies for products and management systems across the world.

As a result from the change of the standard ISO/IEC 17011:2018 and in accordance with the transition period of EA and ILAC, IARM by the end of 2019, should submit their own Self-assessment report to EA (Self assessment report IAF/ILAC-A3:01/2018) indicating how the new requirements of the standard have been implemented.

- Special objectives for enforcement of the Programme are as follows:
 - Increase in the number of bodies accredited by 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 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 the realization of international projects.

The fulfillment of the Programme objectives will be ensured through the funds provided in the 2019 Budget of RM, as well as through participation in projects, such as: TAIEX Instrument of the European Commission, PTB and others.

III. Envisaged activities for Program implementation

The 2019 Budget of Republic of Macedonia, Section 10001 – Ministry of Economy, Sub-programme 51 – IARM, for categories 40 – salaries and compensations, 42 – goods and services, 46 – subsidies and transfers, and 48 - capital expenditure, has envisaged funding in the amount of MKD 9.163.000,00 for the account 637/603, MKD 28.000.000,00 for the account 631 or a total of MKD 37.963.000,00.

- Approximately 23% of the funds are intended for salaries of the employees from the Budget of the Republic of Macedonia – account 637/603 IARM.
- Approximately 71% of the funds are intended for goods and services on the account 637/603 and 631 IARM.
- Approximately 3% of the approved funds are intended for subsidies and transfers (for severance pay prior to retirement)
- Approximately 3% of the funds are intended for capital expenditures.

For the purpose of reviewing and 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

In the official register of IARM, at the moment of preparation of the Program, there are 180 active accredited conformity assessment bodies, and 7 new applications for accreditation have been received. In 2019, 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 revise, 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 the concerned parties, supported by the work of the Technical Committees and the same will be developed depending on the interest of the concerned parties.

In the course of 2019, a raise in the number of applications for accreditation is expected, especially from the certification bodies for management systems, and for that area, IARM expanded the scope of the EA-MLA Agreement.

Also, during 2019, accreditation activities abroad will also continue, at the same time observing the rules on cross-border accreditation.

Required funding.....MKD 19.900.000,00

3. Organization of trainings

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

At the time of the Programme preparation, the List of active assessors and experts consists of: 19 lead assessors and 2 lead assessors-in-training, 64 technical assessors, 7 assessors-in-training and 39 experts. Seven of the lead assessors are employees in 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 fulfill 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 its efforts 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 2019 on organizing and participating in trainings, seminars and workshops of assessor candidates and technical assessors, as well as trainings with participation in surveillance assessments.

In 2019, IARM plans to organize the following trainings/workshops:

- Training for its staff and members of IARM's Council 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 22870:2016);
- Training on assessment harmonization 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 and on site assessment as per the MKC EN ISO/IEC 17025 in laboratories for food, environment and construction testing;
- Training for assessors - on site assessment as per the standard MKC EN ISO/IEC 17021-1;
- Training for Protected Designation of Origin, Protected Geographical Indication, Guaranteed Traditional Specialty;
- Training for sampling as independent activity
- Training for flexible scope of accreditation
- Training for assessment and accreditation of opinions and interpretation
- Training for the requirements of the standards: ISO 50001 and – ISO 13485, ISO 9001:2015 and IAF MD documents and ISO 14001
- Training for Assessors in the field of organic production (incl. all of its specifics), in particular organic production in third countries;
- Training for assessment of the impartiality and confidence in conformity assessment bodies
- 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).
- Workshop/Training/Exchange of good practices: Implementation of EA-2/17
- Workshop for the Regulation (EU) No. 305/2011 (Construction products)
- Training for the risk management standard (Risk management – Guidelines).

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..... MKD 1.500.000,00

- **Human resources**

The Institute for Accreditation of the Republic of Macedonia has a total of 17 regular employees.

Required fundingMKD 8.783.000,00

3. 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..... MKD 100.000,00

4. Internal Audit

Pursuant 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. The internal audit in 2019 will be conducted according to the new revised standard MKC EN ISO/IEC 17011:2018, whereby the internal auditors will focus on the key differences that need to be implemented in the documents for the management system of IARM.

5. 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, review of IARM management 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 goals of IARM, and to examine the efficiency of IARM's quality management system through analysis of documents, reports, complaints, appeals, remarks and non-conformities.

6. 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, familiarization 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 2018 Annual Report on the IARM's Operation,
- Promotion of the certificates awarding to accredited bodies in 2018/19 on June 9th - 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, and
- Organization and/or participation on conferences and other types of meetings on topics of importance for the accreditation and
- Development, maintenance and upgrade of the official web-site of IARM.

Required funding.....MKD 1.620.000,00

7. 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 Supervision Board is composed of 3 members.

Required funding.....MKD 1.700.000,00

8. 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 2019 are as follows:

- as a full member of EA, and for the acquired MLA Agreement signatory status, IARM has to pay an annual membership fee of EUR 10.769,00,

- as a full member of ILAC, and for the acquired MRA Agreement signatory status, IARM has to pay an annual membership fee of AUD 3.000,00,
- as a full member of IAF, and the acquired MLA Agreement signatory status, IARM has to pay an annual membership fee of USD 1.588,00.

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 Agreements 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.....MKD 2.600.000,00

9. Management and current operation of IARM

For the regular delivery of IARM's activities, IARM's Budget for 2019 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..... MKD 1.760.000,00

IV. Final provisions

1. As at 31.03.2020, IARM shall submit a Report containing the financial indicators for implementation of the 2019 IARM Working Program to the Government of the 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 the Republic of Macedonia".

Number:44-11462/1-18

Date:22 January 2019

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