



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

**WORKING PROGRAM
of the Institute for Accreditation
of the Republic of Macedonia for the year 2016**

Act: PR 2016

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 the 05th January 2016 adopted the following

Working Program of the Institute for Accreditation of the Republic of Macedonia for the year 2016

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. The basic condition of accreditation is for the subject to apply in its activities particular standard/standards from the MKC EN ISO/IEC 17000 and MKC EN ISO 15189 series.

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

- With the European Cooperation for Accreditation (EA) signed the EA-MLA (Multilateral agreement – MLA¹);

- With the International (Global) Laboratory Accreditation Cooperation (ILAC) signed the ILAC-MRA (Mutual Recognition Arrangement- MRA²) and
- With the International Accreditation Forum (IAF) signed the IAF-MLA Multilateral agreement – MLA³).

By signing these Agreements, the IARM opened the gates to the European and world market following the principle “accredited once, accepted everywhere”.

The signing of the Agreements shall mean that the issued documents by the Macedonian accredited conformity assessment bodies, in accordance with the Standards 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 2016

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. Namely, the main target of the activities of the IARM in 2016 will be maintenance and upgrading the system for quality maintenance, as an essential condition for supporting the contracts.

¹ 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.

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

³ 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;
- Work on its own 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 organization;
- Continuous work 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 2016, and also through participation in projects such as: The Regional Project "Promotion of the regional cooperation in South- Eastern Europe in the field of infrastructure of the quality" (PTB) financed by the German Institute for Metrology, TAIEX Instrument of the European Commission etc.

III. Envisaged activities for enforcement of the Program

The Budget of the Republic of Macedonia for 2016 ("Official Gazette of the Republic of Macedonia" No 180/13), section 10001 – Ministry of Economy, in the subprogram 51 – IARM, categories 42 – goods and services and 46 – subsidies and transfers and 48 - capital expenditure has planned funds in the amount of 30.780.000,00 MKD.

For the establishment and maintenance of an efficient national accreditation system in accordance with the Law on Accreditation, the standard MKS EN ISO/IEC 17011, as well as the

rules of the European cooperation for Accreditation and the International Laboratory Accreditation Cooperation (EA, ILAC and IAF), the following activities need to be carried out:

1. Accreditation activities

IARM has so far accredited 174 conformity assessment bodies and has 30 new pending applications for accreditation. In 2016 a regular surveillance over the accredited bodies will be carried out and IARM shall work on the pending applications for accreditation which implies increase in the number of accredited conformity assessment bodies.

In accordance with the new Law on Accreditation as well as the obligations arising from the signed international agreements, the IARM shall continuously maintain and improve the overall accreditation system. Within the activities for development, the IARM shall develop new accreditation schemes and areas pursuant to the specific needs of the Republic of Macedonia, such as the accreditation of certification bodies for personnel, organizers of competence testing, certification bodies for construction products, for which the primary activities for competent assessors training have already started. The development of these schemes and areas shall be in cooperation with the interested parties, supported by the work of the Technical Committees.

IARM's work priority in the course of 2016 will be implementation of the Government of Republic of Macedonia's projects, connected directly to the accreditation procedures.

Namely, 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. Within the project, 15 laboratories have been accredited already, whereas part of the others are in the process of accreditation, and one part is still in a process of preparation for their accreditation.

Additionally, it will be continued with the realization of the requirement of the Ministry of Health on accreditation of 8 medical laboratories in Republic of Macedonia according to the standard MKC EN ISO 15189. Simultaneously, IARM will continue to process the current and upcoming applications for accreditation for medical laboratories, including the private sector as well, according to the same standard, which is expected to cause greater interest, especially due to the signing of the EA-MLA Agreement for this area, too.

In the course of the upcoming 2016, a raise in the number of applications for accreditation of certification bodies for system management is expected, according to the regulations of the Law on Establishing a Quality Management System and a Multilateral Framework to Assess Work and Services in Public Administration ("Official Gazette of Republic of Macedonia" No 69/13), according to which the certification bodies that will certify the implementation of ISO 9001 in public institutions, are obligated to be accredited by IARM.

Also, in the course of 2016, accreditation activities are expected to be performed abroad, respecting the regulations of trans-frontier accreditation. Namely, according to the aroused interest, applications for accreditation are expected from the neighborhood (Albania), where IARM has conducted procedures for accreditation of conformity assessment bodies.

2. 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 2015, 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-professionals in the IARM, whereas the rest are external associates, the majority from the Republic of Macedonia. The lists, in addition contain assessors and experts from other accreditation bodies, members in the EA or those having signed cooperation agreements with the IARM.

In 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.

Hence, the forthcoming 2016 year shall also bear particular emphasis on organization of and participation in training, seminars and workshops and participation of the assessor candidates and technical assessors and also trainings including assessments under surveillance.

In 2016, the IARM is planning to organize the following training:

- 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 (ISO 15675);
- Training on harmonization in the assessment of the leading and technical assessors of the IARM.
- Training for accreditation of PT-providers according to the standard ISO/IEC 17043;
- 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 and
- Training on the standard MKC EN ISO/IEC 14001:2015.

These training sessions shall be attended by the IARM staff and the external associates, assessors and experts.

Some of the theoretical training shall be organized in the IARM Training Centre, some in the international accreditation bodies, members of EA, signatories of the MLA.

Also, the Annual training plan for the staff considers realization of generic and specialized trainings according to the legal requirements for professional upgrade and competence of the administrative workers.

3. Cooperation with the state authorities

Based on the acquired experience from the work, IARM has acknowledged the need for intensifying the cooperation with the public sector. The concept of this is organizing working meetings/workshops for service users of IARM with a special accent on a target group: public sector (ministries of economy, agriculture, forestry and water resource management, education, health, informatics society and administration, Inspection Council, other organs of the state management, management organizations that are directly or indirectly connected to the accreditation).

The concept plans are towards analysis of topics for right approach, treatment and assessment of the importance of the accreditation in realization of their activities, especially in the work of the inspection services, but also in other state authorities that implement in their work regulations in which the accreditation prescribes as a mandatory condition for receiving certain rights for work in the so called regulated and non-regulated area, in which accreditation is performed on a voluntarily request of the service users.

The final aim is an appropriate implementation of the national regulation according to the accreditation demands, as a proper use of accreditation benefits. The expected result is providing a good functioning of the link on relation: economy- enforcement authorities, and will increase effectivity, efficiency and rationality in the work of the public services.

4. Meeting organization for the Multilateral Agreement Committee - EA

The meeting of the Multilateral Agreement Committee EA will be held in October, 2016 in Skopje, where leaders of all national accreditation bodies, that are full-fledged members of the EA, will participate, as well as others who have signed bilateral agreements for cooperation with EA.

IARM as a host-organizer and participant in the event has the obligation to take logistic-organizational activities for its support as following: selection and reservation of the accommodation facility for the participants, providing spatial and technical conditions for work (conference hall provided with accompanied audio-visual equipment, organization of meals and coffee breaks at the time of sessions), working materials, promotional materials for the participants with proposal for facultative visits of locations and their organization and realization, transport organization for welcoming and sending the participants to/from the airport, as well as other logistic activities.

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, shall undertake activities in favor of promotion of the need of accredited and authorized bodies with head offices in the Republic of Macedonia. The promotion of the accreditation system shall be pivotal to the implementation of the projects by the Government of the Republic of Macedonia, such as the project of the Ministry of Education for accrediting the laboratories of the higher education institutions and also the project of the Ministry of Health for accreditation of the 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, i.e. approximation to terms of accreditation. 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 international accreditation organizations;
- Media promotion of accreditation;
- Issuance of an Annual Report on the work of IARM for 2015;
- Ceremony of awarding of certificates to accredited bodies in 2015/16. This promotional event shall take place on the 9th June, on the World Accreditation Day;
- Organization of press conferences;
- Organization of workshops for service users of IARM with a special accent on target group: public sector (ministries of economy, agriculture, forestry and water resource management, education, health, informatics society and administration, Inspection Council, other

organs of the state management, management organizations that are directly or indirectly connected to the accreditation);

- Organization of joint events with the Consumers' Organization of the Republic of Macedonia;
- Organization of joint events with the Economic Chambers of the Republic of Macedonia;
- Organization of meetings with businessmen in several towns throughout the territory of Republic of Macedonia;
- 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 three members. The meetings of the two bodies operating under the IARM are organized when necessary and payment is conducted upon attendance and limited to not more than 12 fees per annum.

9. International activities

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

As a full-fledged member of these three organizations, 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 2016 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.

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, 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 2016 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 vehicle as well as procurement of computer equipment.

11. Final Regulations

1. Inclusive of 31st March, 2017, the IARM shall submit a report containing financial indicators for the implementation of the Work Program of the IARM for 2016, 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".

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Date: 05th January 2016

**Deputy President of the Government
of the Republic of Macedonia
MSc. Zoran Stavreski**