



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

**REPORT on
the realized annual work program of
the IARM for the year 2016**

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I. Introduction

According to the Law on Accreditation, ("Official Gazette of the Republic of Macedonia", No.120/09, 53/11, 41/14 and 53/16), the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM), is a public institution performing activities and tasks of a national accreditation body in the Republic of Macedonia.

The accreditation is an expert procedure by which the IARM, with the given certificate, formally confirms the ability (competence) of the body to perform specific tasks in the field of conformity assessment. Also, the accreditation is an activity of public interest.

The IARM's legal framework is defined by: the Law on Accreditation; the IARM's Statute; the acts of the Council; the acts of the IARM's Director and other records.

Bodies of the IARM:

1. Council
2. Director and
3. Supervisory Board for Material and Financial Affairs.

Within the process of accreditation, the IARM performs the following activities:

- a. Accreditation of testing and calibration laboratories
- b. Accreditation of medical laboratories
- c. Accreditation of bodies performing inspection
- d. Accreditation of certification bodies.

II. Realized activities of the IARM in 2016

According to the Work Program of the IARM for 2016, adopted by the Government of the Republic of Macedonia and published in the "Official Gazette of the Republic of Macedonia" No.02/2016, the IARM has realized the following activities:

1. Accreditation activities

a. Status of accredited bodies

By the end of 2016 a total of 200 conformity assessment bodies were accredited, 167 of which were valid (current) and 33 accreditations were withdrawn or suspended at the request of the bodies or by officio.

In 2016 a total of 23 new bodies for conformity assessment were accredited: 9 testing laboratories, 1 calibration laboratory, 4 medical laboratories, 3 certification bodies for products and 6 inspection bodies.

In 2016, 21 conformity assessment bodies were granted reaccreditation and in other bodies for conformity assessment, the IARM conducted regular surveillance within which cross-border surveillance activities were performed.

The IARM has accredited 2 new certification bodies for building products, according to previously developed scheme for this area.

Also, in 2016 the IARM has started practical implementation of the Procedure for the application of the MKC CEN/TS 15675 in procedure for accreditation of testing laboratories.

In the number of newly accredited bodies for conformity assessment are also included the accredited laboratories in higher education institutions furnished by the Government of the Republic of Macedonia and medical laboratories designated by the Ministry of Health, whose accreditation was foreseen in this government project.

The IARM has also accredited the first laboratory in the field of forensics at the Ministry of Interior.

2. Organization and participation in training

a. In accordance with the Annual Training Plan of the IARM for 2016 and internal training procedures of the IARM, the IARM organized the following trainings:

- Training on the topic: "Accreditation - support of healthy domestic economy and smooth competitiveness of the Macedonian companies on foreign markets", designed for business entities
 - Training for the IARM employees for the application of DMS software at the IARM.
- As a result of the realized trainings, the IARM has built its institutional capacities through education of both regular employees and external collaborators.

b. Project activities

In 2016, the IARM participated in realization of the following international projects:

- PTB – activities

Through the PTB project "Promotion of regional cooperation in South Eastern Europe in the field of quality infrastructure", participation was realized on the following trainings:

- Training for lead assessors and assessors - Training of Trainers (ToT)
- Training for "Accreditation for notification EA 2/17 ISO 17021 for notification by modules (D, E, X)
- Training for requirements of the ISO 17021 -1: 2015
- Within the German cooperation organized by the PTB and GIZ a participation in the Workshop for organic production has been conducted.

- TAIEX-activities

The following activities were realized through the **TAIEX** instrument:

- Training for Accreditation of PT providers.

- Project on infrastructure of the quality for the Western Balkans countries

- Conference on PT patterns for testing of construction materials and electrical tests.

- **EA – trainings**

Organized by the EA, participation on trainings for peer evaluation is realized.

- Organized by the German accreditation body DakkS, a participation in the Training for assessors for Organic production has been realized, in accordance with the standard ISO/IEC 17065.

c. Human resources

The Personnel Evaluation Committee, besides updating files of all members of the list of assessors and experts, monitored the implementation of the plan and training program for assessors, the end result of which is an update of the list of assessors and experts of the IARM, pursuant to the procedures of the European accreditation (EA).

Namely, as a result of the trainings, a strengthening of the competence of domestic assessors and experts from many areas is evident, so in performing the assessments in the assessment teams many domestic assessors/experts are engaged. It was a priority objective of the IARM in all these past years of operation. The engagement of expert assessors from the region amounts to a case of necessity, like a conflict of interest between the evaluator and the conformity assessment body or while developing new accreditation schemes.

Hence follows the conclusion that the IARM fully implements all the activities envisaged under this item of the Work Program of the IARM for 2016.

The IARM staff comprises 18 full-time employees, of which 15 persons have the status of administrative officers. According to the Law on Administrative Officers, the process of evaluating their work is performed. A transformation of contractual arrangement in full-time employment is realized, in accordance with the legislation.

Pursuant to the needs of the IARM and the constant call for assessors, published on the IARM's website in 2016, the number of applications filed for assessors is visibly increased. The list of assessors of the IARM is composed of 20 leading assessors, 50 technical assessors, 10 assessors in training, 8 candidates for assessors and 71 experts. The plan for supervision of the assessors was conducted according to the planned dynamics.

Of the total number of leading assessors, 10 are full-time employees in the IARM.

3. Cooperation with the state authorities of the Republic of Macedonia

According to the Work Program of the IARM for 2016, in the period from September to November 2016, organized by the Institute for Accreditation of the Republic of Macedonia (IARM) the implementation of the ***Project to intensify the cooperation with public sector institutions in the Republic of Macedonia*** took place.

In terms of organization, the realization went through roundtables with the participation of representatives/employees in the public sector who meet the accreditation in their working process.

There were organized three round tables, separately for: laboratories, certification bodies and inspection bodies, each of them including questions related to accreditation, the work of the accredited bodies, the proper treatment and access to the documents issued by them.

Particular attention was paid to the issues of proper treatment and assessment of the importance of accreditation in terms of performance of activities, powers of the public sector, especially the work of the inspection services and other state bodies which in their work apply regulations that accreditation prescribed as a mandatory condition for obtaining certain authorizations for work in the so called regulated area and in the unregulated area in which accreditation is performed on a voluntary request of the service customers. The meetings were led with interactive discussions of participants and lecturers, where the most important issues of the accreditation were discussed from the aspect of the work of the relevant public sector entities.

Considering the quality of the debates inevitable is the summary conclusion that the organization of this kind of activity ensured the IARM achievement of the primary purpose designed for this project, which in hindsight is also possible to be qualified as its ultimate goal, and that is proper implementation of the national legislation related to accreditation requirements as well as proper use of the benefits of the accreditation.

Therefore, also follows the expected effect of providing a smooth functioning of the link route: Economy - bodies of executive power and improvement of the effectiveness, efficiency and cost-effectiveness in the operation of the public services.

Also, during 2016 the IARM participated in the work of several working groups established by the Government of the Republic of Macedonia, the Ministry of Economy, Ministry of Environment and Physical Planning and the Ministry of Agriculture, Forestry and Water Management, Ministry of Transport and connections.

Within the established cooperation between the Federation of Macedonian Chambers of Commerce (MCC) and the Institute for Accreditation of Republic of Macedonia (IARM), a press conference was organized under the title *"Accreditation - support for strengthening the national economy and passport for free exit on foreign markets"*. The conference aims at emphasizing the role of accreditation as an internationally recognized and proven tool for building a healthy and competitive domestic economy and support the idea of free trade, free movement of goods and services worldwide.

Also within this cooperation a training was organized on the following topic *"Accreditation - support of healthy domestic economy and smooth competitiveness of Macedonian companies on foreign markets."* On the training were discussed questions about the importance of accreditation, accreditation procedure, the areas in which it is applied and its benefits for the economy. The ultimate goal of the training was to pay attention to the businessmen for the use of accreditation as an easier way of ensuring greater competitiveness in terms of quality of products and services offered by the domestic and foreign markets.

In 2016, IARM participated in the work of the Technical Committees in the Standardization Institute of the Republic of Macedonia.

4. Organization of the meeting of Committee for multilateral agreements of the European cooperation for Accreditation (Multilateral Agreement Committee EA-MLA)

In the period between 04 and 06 October 2016, the Institute for Accreditation of the Republic of Macedonia (IARM) hosted and was also a participant of the 36th meeting of the Committee for multilateral agreements of the European cooperation for Accreditation (EA-MAC).

The event at the plenary part was welcomed by Mr. Driton Kuci, Minister of Economy at the Government of the Republic of Macedonia.

On the meeting, attended by 70 representatives of national accreditation bodies of countries - full and associate members of the European Cooperation for Accreditation (EA), representatives of the Advisory Council of the EA and representative from the European Commission, were adopted operating decisions of importance for the maintenance and the strengthening of the national systems of accreditation. Pursuant to the Plan and the Work Program of the European Accreditation Organization, it was decided on the meeting that in December 2017, the second regular surveillance assessment of the IARM will take place after signing the EA MLA Agreement and the assessment of the planned extension of the scope for the new area.

The IARM as a host-organizer and participant of the event has fully realized its commitments of logistical-organizational activities for its maintenance, such as: the selection and reservation of accommodation facility for participants, providing spatial and technical working conditions, working material, promotional material for participants with proposed locations for optional visit and their organization and implementation, as well as other logistical activities.

5. Promotion of the accreditation system

In 2016 there were held the following promotional events:

- Under the slogan Accreditation: "Global tool to support the work of the public sector" on 9 June the Institute for Accreditation of the Republic of Macedonia marked the World Day of accreditation with a ceremony;

The event was attended by numerous guests, representatives of the Government, representatives of the public sector, research and educational institutions, health care facilities, associates, representatives of bodies for conformity assessment and journalists;

- As part of the celebration of World Day of accreditation, the IARM issued a brochure under the motto "Accreditation: Global tool to support the work of the public sector." On the event the IARM organized a promotion for granting Certificates for accreditation for the conformity assessment bodies accredited during 2015/16, and also the annual newsletter about the work of the IARM for 2015 was promoted. The event took place at the Hotel Continental in Skopje. The event was covered by adequate media reports;

- In 2016, the IARM issued a regular "Annual Work Report of the IARM in 2015";

- The IARM issued two brochures on topics; "Providing testing, measurement and calibration-difference between accreditation and certification" and "Benefits of the accreditation";

- Press conference on the following topic "Accreditation - support for strengthening the national economy and passport for free exit on foreign markets";

- Realized Project of the IARM to intensify cooperation with the public sector, within which three round tables were held;

- Realized TV and radio programs on topics of accreditation of conformity assessment bodies for national and local media.

6. Operation of the IARM Council and the Supervisory Board of the material and financial operation of the IARM

In 2016 the IARM Council and the Supervisory Board of the material and financial operations of the IARM continued to function newly compiled. Their functioning is of

significant support for the work of the IARM, both in terms of management and in terms of supervisory activities.

Pursuant to accreditation, the IARM Council is composed of 11 members, and the Supervisory Board of the material and financial operations of the IARM of 3 members.

During 2016, the IARM Council held 10 sessions since his term began to run from March 2016. The Supervisory Board of the material and financial operations started working in January 2016, after a long interruption due to expired mandate of the previous composition, and held 12 meetings.

7. International activities

In 2016, the IARM had many international activities:

- The IARM actively monitors and participates in the work of the European Cooperation for Accreditation. The employees from the IARM participated in the work of the Committees of the European Cooperation for Accreditation (EA MAC Committee, Laboratory Committee, Inspection Bodies Committee, Certification Bodies Committee, Horizontal harmonization Committee, Committee for communication and publication as well as in the working groups functioning within different committees.).
- As a full-fledged member, the IARM participated in the work of the International Accreditation Organization (ILAC - International Laboratory Accreditation Cooperation) and the International Accreditation Forum (IAF).
- The IARM timely paid the fees in the form of annual fee for 2016 to the European and World organizations for accreditation, as well as the fees to the International Accreditation Forum.
- The IARM took part in work of the Subcommittee on Trade, Industry, Customs and Taxation as well as in the negotiations for signing of the ACAA Agreement with the European Commission.
- The IARM took part in the working group for accreditation and conformity assessment – expert group for internal market within the European Commission.
- The IARM's assessors participated in trainings organized by the EA for peer evaluation, after which one of the assessors took part in the team of the EA for peer evaluation of the National accreditation body of Portugal.

With the rest of regional accreditation institutes, with which the IARM has already signed bilateral agreements, the cooperation is continuous and ongoing. Within these agreements, the IARM delivered the following activities:

- Participation in joint trainings;
- Mutual witnessing during assessments;
- Shared activities under the regional IPA project ;
- Exchange of experts with the accreditation bodies from Serbia, Croatia and Bulgaria;
- Participation at the regular annual Meeting of the bodies from the region in Belgrade;
- Participation at the Conference of quality in Croatia.

8. Management and current operation of the IARM

The following have been regularly maintained and upgraded: the technical resources necessary for daily duty performance, as well as other ongoing maintenance in order to provide the appropriate conditions to perform the job duties.

Besides the Training for the employees of the IARM, there have been realized regular activities in accordance with the requirements of international standard ISO/IEC 17011, which is the basic standard for the work of the IARM: Internal audit and management review, whose evaluation and final conclusion is that the system introduced for accreditation is a quality and efficient in practice, has given the required results and it should be continually maintained and upgraded.

III. Concluding observations

Based on the foregoing, it can be concluded that the IARM has fully implemented the activities envisaged in the Work Program of the IARM for 2016.

The successful implementation of planned activities is measurable through the increased number of certificates of accreditation, maintenance of existing accreditations, strengthened competencies of the IARM employees and external collaborators, maintenance and improvement of an effective system for managing quality, maintaining the international reputation and status of the IARM (by maintaining the validity of the international agreements: EA -MLA, ILAC-MRA and IAF-MLA), expanding bilateral cooperation with other national accreditation bodies, proper promotion of the accreditation system, trans boundary accreditation activities and parallel active work at home in the realization of capital projects by the Government of the Republic of Macedonia, such as laboratory accreditation in higher education institutions and in public health.

Director
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