



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

**REPORT on
the implementation of the Work program of
the IARM for 2015**

Report on the implementation of the Work program of the Institute for Accreditation of the Republic of Macedonia for 2015

I. Introduction

According to the Law on Accreditation, ("Official Gazette of the Republic of Macedonia", No.120/09, 53/11 and 41/14), 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 inspection bodies
- d. Accreditation of certification bodies.

II. Realized activities of the IARM in 2015

According to the Work Program of the IARM for 2015, adopted by the Government of the Republic of Macedonia and published in the "Official Gazette of the Republic of Macedonia" No.194/2014, the IARM has implemented the following activities:

1. Accreditation activities

a. Status of accredited bodies

By the end of 2015 a total of 180 conformity assessment bodies were accredited, 165 of which were valid (current) and 25 accreditations were withdrawn or suspended at the request of the bodies or by officio.

In 2015 a total of 29 new bodies for conformity assessment were accredited: 11 inspection bodies, 13 testing laboratories, 3 calibration laboratories, 1 medical laboratory and 1 certification body for products.

In 2015, 29 conformity assessment bodies were granted reaccreditation and in other bodies for conformity assessment, the IARM conducted regular surveillance.

Also in 2015, the IARM continued with cross-border activities by conducting a joint assessment for accreditation with the Albanian accreditation body in the Republic of Albania, at their request, and the body proves its competency with a certificate issued by the IARM.

The IARM has developed a scheme for a new area - the certification of building products. For this purpose a plan has been prepared for the expansion of activities for its development, and has already been received an application for accreditation body for this area.

The IARM has prepared a plan of action to change the requirements for accreditation - implementation of the new standard ISO/IEC 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of systems management – Part 1: Requirements.

The IARM has established a Procedure for application of MKC CEN/TS 15675 in accreditation procedure for testing laboratories for waste gases after which training for conformity assessment bodies and assessors was implemented.

b. Project activities

In 2015, 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" a series of participation on trainings and workshops, were conducted, as follows:

- Measuring uncertainty in microbiology and application of the requirements of the standard MKC EN ISO/IEC 17025;
- Training for organic production;
- Training for certification of building products;
- Participation in the Round table of the accreditation bodies of South East Europe;
- Training for flexible scope;
- Organized by the PTB and GIZ projects, a participation in a workshop on regional cooperation for organic production in Sarajevo is realized.
 - Workshop - accreditation of laboratories for testing of gases emission;
 - Training for technical requirements for medical laboratories according to the standard MKC ISO 15189.

❖ TAIEX-activities

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

- Study visit for On-site assessment of medical laboratory in Croatia;
- Workshop on emission of gases according to the technical specification CEN/TS 15675;

- Training for the new standard 17021-1:2015 and application of the IAF documents for accreditation of certification bodies for system management;
- Study visit: Accreditation of PT providers and accreditation of producers of certified reference materials; and
- Study visit for development of certification schemes for construction products and accreditation of LT for construction products.

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

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

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 Ministry of Agriculture, Forestry and Water Management.

The initiated project activities within the project of the Government of the Republic of Macedonia for the implementation of capital projects by the Government for laboratory accreditation of the higher education institutions furnished by the Government of the Republic of Macedonia and for accreditation of 8 medical laboratories designated by the Ministry of Health, continued with regular intensity.

Also, the IARM continued its activities within the Committee for market surveillance.

In 2015, the IARM participated in the work of the Technical Committees within the Standardization Institute of the Republic of Macedonia.

d. Human resources

The Personnel Evaluation Committee besides updating files of all members of the list of assessors and experts, also monitored the implementation of the plan and training program for assessors, and final result of which is an update of the list of assessors and experts of the IARM, pursuant to the procedures of the European co-operation for 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 2015.

The IARM staff comprises 17 full-time employees, of which 14 persons have the status of administrative officers. According to the Law on Administrative Officers, the process of evaluating their work is performed. Meanwhile, a change and compliance of Regulations on

organization and systematization of jobs is performed, with the new legislation under the Law on public employees and the Law on Administrative Officers. A positive opinion is received for them from the competent ministry spring, and as part of these activities were prepared new codes of the jobs involved in the public catalog.

Two transformations of contractual arrangements in full-time employment for an indefinite period are realized in accordance with legislation, as well as harmonization of the laws on the organization and systematization of jobs in IARM, for which were developed codes for jobs in the catalog for the public sector.

Pursuant to the needs of the IARM and the constant call for assessors, published on the IARM's website in 2015, the number of applications filed for assessors is visibly increased and the list of assessors of the IARM is composed of 20 leading assessors, 51 technical assessors, 10 assessors in training, 6 candidates for assessors and 71 expert. 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.

2. Organization and participation in trainings

Pursuant to the IARM's Annual Training Plan for 2015 and its internal training procedures, the IARM organized the following trainings for its employees and external assessors:

- Training for the employees of the IARM on the topic: "Implementation of the standard MKC EN ISO/IEC 17011".
- Harmonization of IARM's assessors.
- Training for medical laboratories, and
- Training for the employees of the IARM on the application of the DMS software of the IARM.

As a result of the realized training courses, the IARM has upgraded its institutional capacities through education of both regular employees and external collaborators.

3. The project „Systems of quality management in Macedonia - problems and solutions" is realized

During 2015, the IARM continues its work on the project entitled "Systems for quality management in Macedonia - problems and solutions" and has completed it successfully.

The project was implemented in the period from June 2014 to January 2016. This project arose from the need to determine the state of the national quality infrastructure in order to provide a qualitative contribution to all organizations that maintain a system of quality management and at the same time will be a guide for all stakeholders regarding accreditation.

The aim was to review the situation and the problems that arise in the implemented systems for quality management, to discover the causes of the problems and propose recommendations to overcome them, to apply the proposed recommendations into practice and to see the results of their application, in other words, the ultimate goal was that the managers can reveal the weaknesses of the existing systems for quality management, to learn how to uncover the reasons for the lack of quality and therefore to provide quality according to the requirements and with the lowest cost of operation.

The project was realized according to the envisaged dynamics and proper scientific research methodology for work, while the IARM was closely cooperating with stakeholders in the country, competent institutions and experts in the field of systems for quality management. Within the project two workshops were held and after their completion the IARM issued a brochure intended. On the final workshop the summarized conclusions were presented as observations and recommendations concerning the effective implementation of the systems for quality management in the businesses.

The successful implementation of the project and the need for its implementation is measured by the achieved positive effects on upgrading the knowledge of managers about quality, and through them on top management of the commercial entities for the right approach and application of systems for quality management in their working environments. As a result the existing systems for quality management in the surveyed industrial enterprises of the country are supposed to improve. Simultaneously it will receive added value because it will also be a guide of the other interested parties in this issue.

4. The following promotional activities were held in 2015:

4.

4. Under the motto “Accreditation: Support in providing of health and social protection” on 9th June, the Institute for accreditation of the Republic of Macedonia celebrated the World Accreditation Day with a ceremony.

The event was attended by numerous guests, representatives of the Government of the Republic of Macedonia, representatives of the health sector, the higher education institutions, associates and representatives of conformity assessment bodies.

- Within the celebration the International Accreditation Day, the IARM issued an appropriate brochure under the motto “Accreditation: Providing confidence in energy supply”. The IARM at the very event organized a promotion of awarding Accreditation Certificates to conformity assessment bodies accredited during 2014/2015 and the Annual Bulletin of IARM’s working operations for 2014 was also promoted. The promotion was held at the Hotel “Continental” in Skopje. The event was covered by adequate media reports.

- In 2015, the IARM issued the regular “Annual Work Program of the IARM for 2014”
- The IARM issued two brochures on the following topics: “Why to use an accredited certification body” and “How Regulators benefit from the accredited certification?”
- A targeted brochure on a subject of its own project “Quality management systems in industrial enterprises - problems and solutions” was issued.
- From 17 to 19 September 2015, in Ohrid, an International Conference on Quality and competency was held. The conference that was organized for the second time in the country has caused wide interest among the stakeholders, especially among laboratories and inspection bodies, as well as state institutions and other entities, stakeholders of the national quality infrastructure and there were presented 35 papers in front of about 120 participants. Among the presented papers are included the two works of the IARM’s employees, which had the dual role of organizer and active participant of the event.

The aim of the conference was to provide a contribution to the development and improvement of the quality and competence of laboratories and inspection bodies, laboratory practice and experience exchange among laboratories, inspection bodies and institutions in the region and beyond and of course improving the overall quality of life.

Within the event, the IARM hosted a regular meeting of the Regional accreditation bodies. The meeting is organized regularly on the basis of agreements on bilateral cooperation of national accreditation bodies in the region and beyond (Serbia, Croatia, Montenegro, Bosnia and Herzegovina, Albania, Kosovo, Turkey, Bulgaria and Russia).

5. Operation of the IARM's Council and the Supervisory Board of the material and financial operations of the IARM

According the Law on accreditation, the IARM's Council is composed of 11 members, while the Supervisory Board of the material and financial operations of the IARM is composed of 3 members.

During 2015, the IARM's Council held 10 meetings, because in October 2015 its mandate had expired. The Supervisory Board of the material and financial operations did not function, because it was not named.

6. International activities

In 2015, the IARM had multiple *international* activities:

- The IARM actively monitors and participates in the work of the European Cooperation for Accreditation. Employees from the IARM participated in the work of the Committees of the European Cooperation for Accreditation (EA Multilateral agreement Committee, Laboratories Committee, Inspection and Certification Committee, Horizontal harmonization Committee).
- 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).
- On April 23, 2015 the IARM officially signed the Multilateral Agreement Arrangement with EA (EA MLA) - An agreement to extend and expand the scope of its importance in the field of accreditation of medical laboratories according to the standard MKC EN ISO 15189. The contract was signed based on the recommendation of the Report of the Working Group EA of the first surveillance visit of the assessment team from EA realized in 2014 that assessed the IARM and after the reported expansion of the scope of the EA MLA agreement for accreditation of medical laboratories.
- On June 22, 2015, an agreement was signed for the use of ILAC-MRA mark between the International Laboratory Accreditation Cooperation (ILAC) and the Institute for Accreditation of the Republic of Macedonia (IARM).
- On September 11, 2015, the IARM became a full member of the International Accreditation Forum (IAF).

In the period from 28 October to 6 November 2015, during the Annual Meeting of ILAC/IAF in Milan, it was officially signed the Agreement for extending and expanding the importance of Multilateral agreement with the World Organisation for Laboratory Accreditation Cooperation (ILAC) Multilateral Recognition Arrangement ILAC-MRA and the field of medical laboratories.

On 05 November, 2015, within the annual meeting of the IAF/ILAC, the IARM as a member of the IAF, signed an agreement for a mutual recognition of the results of certification bodies for products, processes and services (Multilateral Recognition Arrangement) IAF-MLA;

- The IARM timely paid the fees in the form of annual fee for 2015 in the European and World organizations for accreditation, as well as the fees for application in the International Accreditation Forum.
- The IARM took part in the accreditation working group of the Subcommittee on Trade, Industry, Customs and Taxation as well as in the negotiations for signing of the ACAA 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 on 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 Croatia accreditation body.

With all regional accreditation authorities, with which the IARM has already signed bilateral agreements, the cooperation is continuous and ongoing. Within these bilateral 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
- Organization and participation on the Second International Conference on Quality and Competence 2015, in Ohrid, during which a Regular Meeting of the Regional accreditation bodies was held.
- Participation at the regular annual Meeting of the accreditation bodies from the region in Belgrade
- Round table of the regional bodies organized by PTB in Monte Negro.
- Implementation of a shared assessment for accreditation at the request of the Albanian accreditation body.

7. Management and operations of the IARM

Regularly maintained and upgraded: information and other technical equipment, as well as the premises of the IARM, strengthening material resources with the purchase of vehicles and other ongoing maintenance in order to provide the appropriate conditions for performing the job duties.

Realized regular activities in accordance with the requirements of international standard ISO/IEC 17011, which is the basic standard for 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 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 2015. 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 (again confirmed by extending the validity of the EA -MLA, ILAC-MRA, as well as admission to membership in the IAF and the signing of the IAF-MLA contract), maintaining the international reputation and status of the IARM, expanding bilateral cooperation with other national accreditation bodies, proper promotion of the accreditation system, border accreditation activities and the parallel active work at home in the realization of capital projects of Government of the Republic of Macedonia, such as laboratory accreditation in higher education institutions and public health.

Director
Trpe Ristoski, PhD
