



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

**R E P O R T**  
**on the implementation of the Work program**  
**of the IARM for 2014**

# **Report on the implementation of the Work program of the Institute for Accreditation of the Republic of Macedonia for 2014**

## **I. Introduction**

Pursuant to the Law on Accreditation (“Official Gazette of the Republic of Macedonia” No. 120/09, No. 53/2011 and 41/14), the Institute for Accreditation of the Republic of Macedonia (hereinafter: IARM) shall act as a public institution performing works and tasks of a national accreditation body in the Republic of Macedonia.

Accreditation is a professional procedure by the means of which the IARM together with the granted certificate shall formally confirm the competence of the body to perform particular tasks in the area of conformity assessment. Similarly, accreditation is a public interest activity.

The legal framework of the IARM is regulated by: the Law on Accreditation; the Statute of the IARM; the Council Acts; the Acts of the Director of the IARM and by other acts.

Bodies of the IARM are as follows:

1. Council
2. Director and
3. Material and Financial Supervision Board

Under the accreditation process, the IARM shall perform 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. Implemented activities of the IARM in 2014**

In accordance with the Work program of the IARM for 2014, adopted by the Government of the Republic of Macedonia and published in the “Official Gazette of the Republic of Macedonia” No. 08/2014, the IARM implemented the following activities:

### **1. Accreditation activities**

#### **a. Status of accredited bodies**

By the end of 2014, a total of 149 conformity assessment bodies were accredited. Nineteen of them have had their accreditation withdrawn or suspended.

In 2014, a total of 17 conformity assessment bodies were accredited:

<b>Type of body</b>	<b>Name of the Body</b>
Inspection body MKC EN ISO/IEC 17020	TEHNICKA SIGURNOST – BMV – Skopje Inspection department
Inspection body MKC EN ISO/IEC 17020	DPTU ENERGO-INSPECT DOO Ohrid
Inspection body MKC EN ISO/IEC 17020	DPTI TEHNICKI CENTAR ZA KVALITET DOOEL Skopje
Inspection body MKC EN ISO/IEC 17020	TDPTU Nedeljkovikj DOOEL export- import Skopje Inspection Body Nedeljkovikj Skopje
Inspection body MKC EN ISO/IEC 17020	DPTU SUPER AUTO KONTROL DOOEL SUPER AUTO KONTROL Vehicle Centre
Inspection body MKC EN ISO/IEC 17020	Inspection body for electrical measurements and examinations in TEHNOINSPEKT D.O.O. SKOPJE
Inspection body MKC EN ISO/IEC 17020	ELEKTROVIN DOOEL Vinica
Testing laboratory MKC EN ISO/IEC 17025	RZ Tehnicka kontrola AD, Skopje
Testing laboratory MKC EN ISO/IEC 17025	CT GLOBALTEST dooel Sofia TESTING CENTRE GLOBALTEST
Testing laboratory MKC EN ISO/IEC 17025	Ss. Cyril and Methodius University Faculty of Mechanical Engineering Skopje Testing laboratory for mechanical characteristics, machines and vehicles
Testing laboratory MKC EN ISO/IEC 17025	State University in Tetovo, Faculty of Applied Science Laboratory for testing and control of construction materials
Calibration laboratory MKC EN ISO/IEC 17025	“GCS MAKEDONIJA” doo Skopje Calibration laboratory “Loviko”
Calibration laboratory MKC EN ISO/IEC 17025	“Public Health Institute of the Republic of Macedonia” Ionizing Radiation Laboratory- Calibration Unit
Calibration laboratory MKC EN ISO/IEC 17025	“Farmahem” DOOEL, SKOPJE Environment Laboratory- calibration depratment
Medical laboratory MKC EN ISO 15189	PZU Opsta bolnica(PHI General Hospital) RE- Medika Skopje Diagnostic biochemical laboratory IVF laboratory
Medical laboratory MKC EN ISO 15189	PZU Avicena Laboratorija- Skopje
Certification body MKC EN 45011	AGRIBIOCERT MAKEDONIJA Product certification body

In 2014, 19 conformity assessment bodies were granted re-accreditation and a total of 96 remaining conformity assessment bodies have had their regular surveillance visits performed by the IARM.

Also, in 2014, the IARM continued its cross border activities.

#### **b. Project activities**

In 2014, the IARM participated in the implementation of the following international projects:

Through the IPA Regional project, IARM's employees participated in:

- Training on product scheme certification in voluntary area, held in Spain
- Training on the new version of the ISO 17065:2012 standard, held in Milan, Italy

The Regional Project 'Promotion of Regional Cooperation in South Eastern Europe in the Field of Quality Infrastructure' targeting the accreditation ~~authorities~~ bodies of Macedonia, Serbia, Albania, Montenegro, Bosnia and Herzegovina and Kosovo, financed by the German Institute for Metrology, encompassed the following activities:

The IARM organized and participated in the Round table of the accreditation bodies from South Eastern Europe - Annual exchange of experiences held from 18<sup>th</sup> to 20<sup>th</sup> February 2014 in Skopje.

The purpose of the event was sharing experiences on important topics and current issues in the field of accreditation, in order to strengthen the quality infrastructure. Within the plenary discussions on specific issues, the conclusions of common interest and importance were identified and summarized in order to achieve harmonization of national legislations, whose ultimate goal is to reduce the technical barriers to trade exchange.

The Round table was attended by representatives of the accreditation ~~authorities~~ bodies of Macedonia, Albania, Bosnia and Herzegovina, Kosovo, Serbia, Croatia and Montenegro, whose countries are also members of the CEFTA Agreement.

Also, through the PTB project, the employed assessors of the IARM as well as the external assessors participated in:

- Training on the MKC EN ISO / IEC 17065: 2012 standard,
- Debate on exchange of experience of assessors for the MKC EN ISO / IEC 17020: 2012 standard
- Training on EU legislation and accreditation of food testing laboratories.

Through the German Society for International Technical Cooperation (GIZ) a participation in a regional event for quality infrastructure was realized.

Organized by the European cooperation for Accreditation (EA) and Germany's National Accreditation Body (DAkkS), in Berlin, Germany, a participation in an Organic Production Training was realized.

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

The IARM participated in the work of several working groups under 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.

The IARM continued its commenced project activities in the project of the Government of the Republic of Macedonia “Macedonian Sun” with the regular intensity. At the same time, the IARM realized activities for implementation of the major projects of the Government of RM for accreditation of laboratories of higher education institutions, equipped by the Government of the Republic of Macedonia and for accreditation of 8 medical laboratories determined by the Ministry of Health.

Also, the IARM continued to participate in the work of the Market Monitoring Committee and maintained the cooperation with the economic chambers in the Republic of Macedonia.

In 2014, the IARM took part in the work of the Technical Committees in the Institute for Standardization of the Republic of Macedonia.

### **d. Human resources**

The Personnel Evaluation Committee continued updating the files of all members of the list of assessors and experts and monitored the implementation of the Plan and Program for training of assessors, which is expected to result in the upgrade of the list of assessors and experts of the IARM, pursuant to the procedures of the European cooperation for Accreditation (EA).

As a result of the trainings, strengthening the competence of the national assessors and experts from different areas is evident, so when conducting assessments a greater number of domestic assessors / experts are engaged in the assessment teams. This was a priority goal of IARM in all these past years of operation. The engagement of assessors - experts from the region is reduced to cases of great necessity, such as conflict of interest between the assessor and the conformity assessment body or development of new accreditation schemes.

On the basis of the foregoing, the IARM fully implemented all activities envisioned under this item of the Work Program of the IARM for 2014.

The staff of the IARM is composed of 15 regular employees, of whom 13 have a status of civil servants. In accordance with the Law on Civil Servants, a process of evaluation of their performance was also carried out. Meanwhile there was an amendment to the Accreditation Law regarding its compliance with the new legislation pursuant to the Law on employees in the public sector and the Law on Administrative Officers. However, despite this formal legal compliance in the proceedings to harmonize the acts on the organization and systematization of jobs a problem was encountered regarding proper qualification and classification of jobs under the new laws and the Catalogue of jobs due to the specific activity of the IARM and categorization of the status of the employees. In order to overcome the problem, an opinion from the Ministry of Information Society and Administration was requested, and the procedure is still ongoing.

In compliance with the IARM’s arising needs and the permanent advertisement for assessors, published on the IARM’s webpage, in 2014 the number of submitted applications for assessors is significantly greater and the List of IARM’s assessors is comprised by: 19 leading assessors, 48 technical assessors, 11 assessors-trainees, 6 candidates for assessors and 60 experts. The assessors surveillance plan was implemented according to the planned dynamics.

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

## **2. Realization of the first regular surveillance after signing the Agreement for mutual recognition of accreditation certificates with the European cooperation for Accreditation (EA-MLA)**

Apart from the current accreditation activities, and the regular maintenance and strengthening of the IARM's quality management system according to the requirements of the Standard MKC EN ISO/IEC 17011 and other standards, in 2014 the IARM finished the preparations to realize the first regular surveillance by the European cooperation for Accreditation (EA-MLA) subsequent to the signing of the Agreement for mutual recognition of accreditation certificates (Multilateral agreement – EA-MLA). The surveillance was conducted in two parts from objective reasons, that is, EA problems in making the assessment team. The first part of the surveillance assessment took place from 9 to 15 March 2014 and the second from 01 to 04 July, 2014. The subject of the surveillance assessment was the declared expanding of the scope of the EA MLA Agreement for accreditation of medical laboratories.

The surveillance assessment resulted in a total positive assessment of the work of the IARM both under the current validity scope of the Agreement and for the newly declared scope of medical laboratories. Only 2 non-conformities were identified, 12 remarks and 12 comments, and they are entirely removed. The Report of the Working Group of EA contains a recommendation to expand the scope of the Agreement for the area of accreditation of medical laboratories under the MKC ISO 15189 standard. The official signing of the Agreement is expected to take place at the upcoming meeting of the EA MAC Committee which will be held in April 2015 in Istanbul.

Concerning organization, the IARM covered the expenses for transport, accommodation and meals for the six-member - assessors team.

## **3. Organization and participation in trainings**

Pursuant to the IARM's Annual Training Plan for 2014 and the internal procedures for training for the IARM's staff, the IARM organized the following trainings for its employees and external assessors:

- Training for the employees of the IARM on: "Implementation of the MKC EN ISO / IEC 17011
- Harmonization of the IARM assessors involved in the assessment of peer-evaluation for EA-MLA
- Workshop for leading and technical assessors of the IARM on the application of the standard MKC EN ISO / IEC 17020: 2012
- Training for the employees of the IARM on the application of the DMS software of the IARM.

Organized by the Ministry of Agriculture, Forestry and Water Economy, employees of the IARM participated in:

- Training on "Deficiencies identified in the environmental sector"
- Training for control / supervision of the control / certification bodies

- Seminar on the European regulation on organic production and the role of the competent institutions.

Organized by the Institute for Reference Materials within the European Commission, participation in the following training was realized: Analysis of contaminants in food and animal feed - Legal and research aspect; including validation of methods and measurement uncertainty.

Organized by the ISRM, participation in Training on Amendments to the 9001: 2015 Standard was realized.

As a result of all previously mentioned training workshops, the IARM achieved significant institutional strengthening through education of the regular employees and of the external associates.

#### **4. Promotion of the accreditation system**

In 2014, the following promotional events were organized:

- On 9<sup>th</sup> June, the Institute for Accreditation of the Republic of Macedonia celebrated the World Accreditation Day with a ceremony under the motto “Accreditation: Delivering confidence in the provision of energy”.

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

- As part of the marking 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 2013/2014 and the Annual Bulletin of IARM’s working operations for 2013 was also promoted. The promotion was held at the Holiday Inn Hotel in Skopje. The event was reported by the media and the first official video on the work of the IARM was promoted. Due to the interest shown, apart from the translation in English, the video was also translated into Russian for the needs of the Russian-speaking countries. This interest resulted from the activities within the establishment of cooperation between the IARM and the Russian accreditation service.

- In 2014, the IARM issued the regular “Annual Work Program of the IARM for 2013”

- The IARM issued two brochures on the following topics: “Accreditation in Europe- Facilitating the harmonization with the regulations and the international trade ”and “ISO 15189- accreditation of medical laboratories.”

- Interview with the Director and employees of the IARM for a **TV show** on topics of economic character.

#### **5. Work of the Council of the IARM and the Material and Financial Supervision Board of the IARM**

In accordance with the Law on Accreditation, the Council of the IARM is composed of 11 members, whereas the Material and Financial Supervision Board of the IARM of 3 members.

In the course of 2014, the Council of the IARM held 12 meetings, whereas for the Material and Financial Supervision Board a new composition is to be appointed. The members' term of office expired in November 2013. The Government was timely informed with three official letters on the necessity to appoint new members of the Board. This procedure is still ongoing.

## **6. International activities**

In 2014, the IARM had multiple international activities:

- The IARM actively monitors and participates in the work of the European Organization for Accreditation and the Multilateral Agreements Committee. Employees from IARM participated in the work of the Committees of the European Organization for Accreditation (EA MAKC, Laboratories Committee, Inspection Bodies Committee, Certification Bodies Committee).

- As a full-fledged member, the IARM participated in the work of the International Accreditation Organization (ILAC - International Laboratory Accreditation Cooperation).

- The IARM timely paid the fees in the form of annual fee for 2014 in the European and world organizations for accreditation.

- The IARM participated in the work of the Subcommittee on Trade, Industry Customs and Taxation as well as in the negotiations for signing of ACAA with the European Commission.

- The IARM signed a Memorandum of Understanding and Cooperation with the Federal Accreditation Service of the Russian Federation. The Memorandum was signed within the Eighth Intergovernmental Russian-Macedonian Commission on Trade, Economic and Scientific-Technical Cooperation held on 29th and 30th September 2014 in Kaliningrad, the Russian Federation.

With all regional accreditation ~~authorities~~ bodies, with which the IARM has already signed bilateral agreements, the cooperation is continuous and ongoing. Within these foregoing bilateral agreements, the IARM delivered the following activities:

- Participation in joint trainings
- Shared witnessing during assessments
- Shared activities under the regional IPA project
- Exchange of experts with the accreditation bodies from Serbia, Croatia and Bulgaria

- Participation in the Regional Conference on Accreditation in Sarajevo, attended by representatives from the accreditation bodies of Serbia, Montenegro, Kosovo, Albania and Croatia

- Participation at the regular annual Meeting of the accreditation bodies from the region in Belgrade

## **7. Management and current working operations of the IARM**



The IARM project on research of the quality management systems in the industry of the RM was of a moderate intensity of realization from obvious inability due to other engagements.

The information and other technical equipment was regularly maintained and upgraded, as well as the adaptation of the premises of the IARM.

In October 2014, the State Audit Office performed audit of the successfulness, efficiency and effectiveness of the system of financial management and control and internal audit in the IARM. The final assessment was entirely positive, with recommendations for personnel and organizational strengthening of the IARM.

The regular activities were realized as well: Internal Audit and Management Review, whose final conclusion and assessment is that the introductory system for accreditation is a quality one and efficient in practice, providing 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 of the IARM for 2014. The successful implementation of the planned activities is measurable through the increased number of accredited certificates, maintenance of existing accreditations, enhanced competence of the IARM employees and external associates, maintenance and upgrading of an effective system of quality management (again confirmed by the supervisory assessment of EA - MLA), the maintenance of international reputation and status of the IARM expanding bilateral cooperation with other national accreditation bodies, proper promotion of the accreditation system, cross-accreditation activities, as well as parallel active operation domestically in the implementation of the major projects of the Government of the Republic of Macedonia, such as laboratory accreditation in higher education institutions and in public health.

**Director**  
**Trpe Ristoski PhD**

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