



**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 2013**

# **Report on the implementation of the Work program of the Institute for Accreditation of the Republic of Macedonia for the year 2013**

## **I. Introduction**

On the basis of the Law on Accreditation (“Official Gazette of the Republic of Macedonia” No. 120/09 and No. 53/2011), 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.

Authorities/ 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 carry out the following activities:

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

## **II. Implemented activities of the IARM in 2013**

In accordance with the Work program of the IARM for 2013, adopted by the Government of the Republic of Macedonia and published in the “Official Gazette of the Republic of Macedonia” No. 04/2013, the IARM has implemented the following activities:

### **1. Accreditation activities**

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

So far, a total of 133 conformity assessment bodies have been accredited. Thirteen of them have had their accreditation withdrawn.

In 2013 a total of 21 conformity assessment bodies have been granted accreditation as follows:

<b>Type of body</b>	<b>Name of the Body</b>
Inspection body MKC EN ISO/IEC 17020	BALEKS D.O.O. Stip
Inspection body MKC EN ISO/IEC 17020	ENERGY MAINTENANCE SOLUTIONS EMS DOO Skopje
Inspection body MKC EN ISO/IEC 17020	AKADEMIJA BRPS – Skopje, SIZ safety of work, fire and environment
Inspection body MKC EN ISO/IEC 17020	DPUT TM DOO – Stip, Control department
Inspection body MKC EN ISO/IEC 17020	VEPAL DOO Gevgelija /Inspection body for tachographs
Inspection body MKC EN ISO/IEC 17020	‘Ss Cyril and Methodius University’ Skopje Faculty of Electrical Engineering and Information Technologies Inspection body for electrotechnical appliances, installations and equipment
Inspection body MKC EN ISO/IEC 17020	CARGOINSPECT– OPREMA DOOEL Skopje
Inspection body MKC EN ISO/IEC 17020	TECHNICAL INSTITUTE DOOEL Negotino
Inspection body MKC EN ISO/IEC 17020	‘KARGOINSPEKT–AGRAR’ d.o.o. Skopje
Inspection body MKC EN ISO/IEC 17020	TEHNICKA SIGURNOST – BMV – Skopje Inspection department
Testing laboratory MKS EN ISO/IEC 17025	Stewart Inspect Skopje – Laboratory services
Testing laboratory MKC EN ISO/IEC 17025	PHI Centre of Public Health Ohrid Laboratory of sanitary chemistry Laboratory of sanitary microbiology
Testing laboratory MKS EN ISO/IEC 17025	MINISTRY OF AGRICULTURE, FORESTRY AND WATER ECONOMY State Phitosanitary Laboratory SPL
Testing laboratory MKC EN ISO/IEC 17025	RI-OPUSPROEKT doo – Skopje
Testing laboratory MKC EN ISO/IEC 17025	Ss. Cyril and Methodius University in Skopje Faculty of Medicine in Skopje Institute of Medical and Experimental Biochemistry Biochemical analyses laboratory (BAL)
Testing laboratory MKC EN ISO/IEC 17025	Centre for Public Health Stip PHI Department of Hygiene and Environmental Protection Laboratory of sanitary chemistry Laboratory department
Testing laboratory MKC EN ISO/IEC 17025	DPTU VINIKIDS dooel, Skopje Laboratory of testing ionizing radiation VINILAB
Testing laboratory MKC EN ISO/IEC 17025	GEOKONTROL DOOEL, Strumica

Testing laboratory MKC EN ISO/IEC 17025	METLAB GLOBAL DOOEL Company for gold analyzing and other precious metals
Medical laboratory MKC ISO 15189	PHI ADRIALAB Skopje Diagnostic biochemical laboratory
Certification body MKC EN ISO/IEC 17021	MKD Sertifikat Inspection body at AM CERT dooel Skopje

In 2013, 17 conformity assessment bodies have been granted re-accreditation and the total number of remaining 83 conformity assessment bodies have had their regular surveillance visits performed by the IARM.

In 2013, the IARM accredited the first medical laboratory in our country on the basis of a submitted application and in compliance with the standard MKC ISO 15189:2010, as a fundamental standard of medical laboratories.

The IARM in the course of 2013 continues its cross border activities.

### **b. Project activities**

In 2013, the IARM has been engaged in the implementation of the following international projects:

Through the initiated IPA Regional project, IARM's employees participated in the training 'Post PT Providers' and within this project the first International Conference 'Quality and Competence 2013' was organized, including a Round table – Regional meeting of the accreditation bodies'.

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

- Training on the Document EA 1/22 on new sector accreditation schemes
- Training on 'Information on EU-Requirements on preparing reports on assessment of control/certification bodies in the organic agricultural production scope'
- Audit of ISO/IEC 17021:2011 and application in a regulated area.
- Round table aiming to exchange experiences of accreditation bodies, participants in this project.

Organized by the European cooperation for Accreditation, the staff of the IARM participated in training sessions as follows:

- EA training on ISO/IEC 17065:2012
- Training of EA assessors.

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

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.

IARM continued with active participation in the project of the Government of the Republic of Macedonia “Macedonian Sun”, which is of pivotal role, and in the process of accreditation of laboratories of higher education institutions, equipped by the Government of the Republic of Macedonia. The process has already commenced and IARM in cooperation with the Ministry of Education and Science carried out preliminary surveillance visits to the laboratories. According to the analyses of approximately 80 public higher education institutions, accreditation of approximately 50 newly-formed laboratories has been envisaged.

Also, the IARM in cooperation with the Ministry of Health, started the process of accrediting 8 medical laboratories. Preparations for their accreditation have been intensified throughout the second half of the year, the IARM participates actively in the creation of this project and determining directions for the project’s promotion.

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 2013, the IARM took part in the work of the Council and the Technical Committees in the Institute for Standardization of the Republic of Macedonia.

#### **d. Human resources**

The Personnel Evaluation Committee continued with updating the files of all members of the list of assessors and experts and designed a 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). The Committee has also designed a Plan for realization of surveillance of assessors, which was successfully carried out.

On the basis of the foregoing, the IARM fully implemented all activities envisioned under this item of the Work Program of the IARM for 2013.

The staff of the IARM is composed of 16 regular employees, of which 14 have attained the status of civil servants. In accordance with the Law on Civil Servants, a process of evaluation of their performance was also carried out.

In compliance with the IARM’s arising needs and the permanent advertisement for assessors, published on the IARM’s webpage, in 2013 the number of submitted applications for assessors is significantly greater and the List of IARM’s assessors is comprised by: 66 assessors out of them 18 are leading assessors, 34 technical assessors from different fields and 14 technical assessors-trainees, 6 candidates for assessors and 40 experts. From the total number of leading assessors, 10 are full-time employees in the IARM.

#### **1. Preparation for first regular surveillance by EA after signing the EA-MLA agreement**

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 2013 the IARM dedicated fully to thorough 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. The main activity was auditing the documents of the IARM’s quality management system, thereby the regulations on the IARM’s working operations have been adequately modified and amended through cooperation, coordination and providing flow of

information with the management and the IARM's staff and the expert opinions by the Technical committees of IARM. The documents audit was carried out into several stages, thereby some of the documents have been modified and amended even twice, the total number of processed documents was 7 under the supervision of the Council of the IARM and 7 documents under the supervision of the IARM's Director. Apart from this, the Council of the IARM has reached 2 new work regulations of IARM.

An integral part of the preparations is the employees' participation in professional trainings and workshops.

The aim of surveillance by the EA assessors team was to be realized in October 2013, i.e. two years following the realization of the initial assessment, nonetheless, the stated was postponed and is going to be realized in the period from 09<sup>th</sup> to 15<sup>th</sup> March 2014, upon EA's request. Concerning organization, the IARM covers the expenses for transport, accommodation and the meals for the five-member- assessors team.

The IARM as a full-fledged member of International Laboratory Accreditation for Cooperation – ILAC and a signatory of the Agreement on multilateral recognition of accreditation certificates with this organization (ILAC-MRA), in November 2013, the IARM signed the Agreement on the right to use ILAC-MRA's mark.

## **2. Organization of training**

Realizing the needs of adequate professional and timely notification of the conformity assessment bodies as to the harmonization of the performance of the accreditation activities to fit the amendments, modifications and revisions of the standards, the IARM in 2013 organized training for various target groups such as: the conformity assessment bodies and assessors (employees in the IARM and external).

Pursuant to the IARM's Annual Training Plan trainings for 2013 and the internal procedures of training the IARM's staff, the employees participated in the following trainings:

- Workshop on application of the new Standard MKC EN ISO/IEC 17020:2012 intended for IARM's employees
- Training on leading assessors of laboratories and inspection bodies
- Training on implementation of the new Standard MKC EN ISO/IEC 17020:2012 for “bodies performing inspection and inspection methods for tachographs and taximeters” in correlation with the Standard MKC EN ISO/IEC 17020:2006
- Training on “measurement traceability and calculations of the measurement uncertainty during calibration of instruments aided by reference materials and noise measuring instruments”
- Seminar on pressure equipment
- Training on accreditation, inspection and certification of products with Geographic Indications and
- Training on health protection and safety in working conditions – for all employees of the IARM.

Having the same objective, and within the established cooperation with the Macedonian Association of Laboratories MAKLAB, in joint cooperation with the IARM, the following two training workshops were organized:

- Training on application of the Standard MKC EN ISO/IEC 17025:2006 and

- Training on “Application of the International Standard MKC ISO 15189:2010- accreditation of medical laboratories“.

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

- Training on the accreditation system: Polish examples and
- Seminar on protection of quality.

Organized by the Croatian Association of Laboratories CROLAB, we have participated also in the Regional workshop on conformity assessment and Competence of laboratories.

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.

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

In 2013, the following promotional events were organized:

- On 10<sup>th</sup> June 2013 the International Accreditation Day was marked as well as the 10<sup>th</sup> anniversary of establishment and working operations of the IARM, as a single national accreditation body. By marking the International Accreditation Day, the IARM issued a brochure under the motto ‘Accreditation-Facilitating World Trade’. The IARM at the very event organized a promotion of awarding Certificates for accreditation to conformity assessment bodies accredited during 2012/2013, the annual Bulletin of IARM’s working operations for 2012 was also promoted, sublimating the IARM’s working operations in a form of monograph for the first decade jubilee 2003-2013. The promotion was held at the hotel Holiday Inn in Skopje, whereas the promotional activities continued in three other towns on the territory of Macedonia. The event was followed by the media.

- In 2013, the IARM issued the regular “Annual Work Program of the IARM for the year 2012”
- The IARM issued a brochure on ‘Why become an Accredited Laboratory’ and ‘Why become an Accredited Inspection Body’ which were promoted within the promotional campaign of the accreditation system of R.M. in Tetovo, Stip and Bitola, followed by the media
- The IARM issued a “Assessor Guide” – second edition
- The International conference “Quality and Competence 2013” was organized in Ohrid. 35 expertise papers, including the expertise paper by the IARM’s staff were presented at the conference. Within the Conference, the IARM organized the regular Regional meeting of regional accreditation bodies. The event was followed by the media.

### **4. 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 2013, the Council of the IARM held a total number of 13 regular meetings, whereas the Material and Financial Supervision Board 12. The members' term of office expired in November 2013. The Government was timely informed on the necessity to appoint new members of the Board, this procedure is still ongoing.

## **5. International activities**

In 2013, IARM had multiple international activities:

- IARM actively monitors and participates in the work of the European Organization for Accreditation (EA). Employees from IARM participated in the work of the Committees of the European Organization for Accreditation (Laboratories Committee, Inspection Bodies Committee, Certification Bodies Committee, Communication and Publication Committee, Harmonization Committee, Multilateral Agreements Committee).
- 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.
- IARM participated in the work of the ILAC (International Laboratory Accreditation Cooperation), in which IARM has acquired the status of a full-fledged member.
- The IARM concluded Agreements on Cross border cooperation with the German accreditation body - DAkkS and with the United Kingdom Accreditation body - UKAS.

During 2013, the procedure for signing of the Bilateral Cooperation Agreement with the Russian accreditation authority, as a national accreditation body of the Russian Federation was continued. With all regional accreditation authorities, 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
- Organization and participation at the International Conference Quality and Competency 2013 in Ohrid
- Participation at the Regional Conference on Accreditation 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
- Working visit to the Accreditation body of Moldova.

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

The Council of the IARM pursuant to the Law on Accreditation carried out a procedure to appoint a director of the IARM by announcing an open call. On the basis of the Report on the Commission on carrying out the procedure for appointing director, the Council of IARM on the meeting held on 10<sup>th</sup> December 2013, reached the Decision on appointing the candidate PhD



Trpe Ristoski for director of the Institute of Accreditation of Republic of Macedonia, with a 4-year term of office.

The reached Decision for appointing PhD Trpe Ristoski for Director of the Institute of Accreditation of Republic of Macedonia, was despatched to the Government of the Republic of Macedonia in order to be approved by the stated. After the received consent by the Government of the Republic of Macedonia the subject decision became enforceable.

On the basis of the decision by the Government of the Republic of Macedonia as of 01<sup>st</sup> October 2013, the IARM moved to new official premises, for the adjustment and realization of the transfer an amendment was added to the IARM's Annual Procurement Plan for 2013, after which adequate public procurements were carried out. The change of the official seat was noted in the IARM's Statute both formally and legally.

The vehicle delegated through the Agency for Management of Confiscated Property was being currently maintained.

On the basis of the foregoing, it can be concluded that the IARM totally realized all the activities envisioned in the Work Programme of the IARM for 2013.

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

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