



**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 2012

Report on the implementation of the Work program of the Institute for Accreditation of the Republic of Macedonia for the year 2012

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 technical 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

II. Implemented activities of the IARM in 2012

In accordance with the Work Program of the IARM for 2012, adopted by the Government of the Republic of Macedonia and published in the “Official Gazette of the Republic of Macedonia” No. 12/2012, the IARM has implemented the following activities:

1. Accreditation activities

a. Status of accredited bodies

So far, a total of 114 conformity assessment bodies have been accredited. Eleven of them have had their accreditation withdrawn.

In 2012 a total of 21 conformity assessment bodies have been *granted accreditation* as follows:

Type of body	Name of the Body	Date
Inspection body MKS EN ISO/IEC 17020	Makpetrol-TNG	22.02.2012
Inspection body MKS EN ISO/IEC 17020	VEUS Association of drivers Veles- for tahographs	29.02.2012

Inspection body MKS EN ISO/IEC 17020	VEUS Association of drivers Veles – for vehicles	29.02.2012
Inspection body MKS EN ISO/IEC 17020	CVO- Ohrid (tahographs)	16.03.2012
Inspection body MKS EN ISO/IEC 17020	Mak Vera	28.05.2012
Inspection body MKS EN ISO/IEC 17020	Velkom Trejd	14.06.2012
Inspection body MKS EN ISO/IEC 17020	ASUC- tahographs	06.07.2012
Inspection body MKS EN ISO/IEC 17020	EUROTEST- Bitola (homologation, tahographs)	18.07.2012
Inspection body MKS EN ISO/IEC 17020	AMD- Bitola homologation	09.09.2012
Inspection body MKS EN ISO/IEC 17020	LTA- Petrol servis	19.09.2012
Inspection body MKS EN ISO/IEC 17020	MRT- vagi	10.10.2012
Inspection body MKS EN ISO/IEC 17020	EVN- electric meters	10.10.2012
Inspection body MKS EN ISO/IEC 17020	E-kontrol- IKK	26.12.2012
Calibration laboratory MKS EN ISO/IEC 17025	Bureau of Metrology	04.01.2012
Testing laboratory MKS EN ISO/IEC 17025	University “Goce Delcev”- Stip, University of Agriculture	27.01.2012
Testing laboratory MKS EN ISO/IEC 17025	Prima Lab	16.03.2012
Testing laboratory MKS EN ISO/IEC 17025	Avicena	31.05.2012
Testing laboratory MKS EN ISO/IEC 17025	Agricultural Institute (Wine Laboratory)	30.05.2012
Testing laboratory MKS EN ISO/IEC 17025	CJZ Strumica	22.08.2012
Testing laboratory MKS EN ISO/IEC 17025	Anima-vet	12.09.2012
Certification body MKS EN ISO/IEC 17021	MKS	26.03.2012

In 2012, ten conformity assessment bodies have been ***granted re-accreditation*** and the remaining 72 conformity assessment bodies have had their ***regular surveillance visits*** performed by the IARM.

In relation to the accreditation activities it is of particular importance to emphasize that by the means of signing of the two international agreements with the European Cooperation for Accreditation and the global organization for accreditation, international recognition of the issued reports and certificates by the Macedonian conformity assessment bodies was obtained. In 2012, the IARM accredited a body performing its scope of activity in 31 countries across the world bearing the mark of the IARM.

Similarly, in line with the needs of the beneficiaries of services, the IARM in accordance with its institutional capacities (system and human resources), launched the development of a new accreditation scheme following the standard MKS ISO 15189:2010, as a basic standard for accreditation of medical laboratories. Namely, two applications for accreditation of medical laboratories have been submitted to the IARM, whose accreditation procedure is ongoing, compliant with the procedures of the IARM.

b. Project activities

In 2012, the IARM has been engaged in the implementation of three international projects as follows:

The initiated IPA National project (Pre- accession assistance instrument, Component 1, Project 3.01 Free movement of goods – Infrastructure for quality) ***“Technical assistance for capacity building of the Institute for Accreditation (IARM)”*** continued with the implementation in line with the envisaged plan and dynamics, thus being brought to an end on 30th July 2012. The project was implemented by the consortium composed of the “Federal Institute for Materials Research and Testing“ (BAM) from Germany, the Institute for Accreditation from Lithuania (LA), and the national accreditation authority for the Federal Republic of Germany (Dakks).

Within the Project in 2012, a total of 7 training sessions amounting to a total of 18 training workshops were carried out as follows:

- Training on the Standard MKS EN ISO/IEC 17021:2011 “Conformity assessment – General requirements for bodies performing quality systems certification”
- Training on the Standard MKS EN ISO/IEC 17024:2003 “Conformity assessment -- General requirements for bodies operating certification of persons“;
- Training about EMAS verifiers;
- Training of trainers;
- Training on the Standard MKS ISO 15189 (medical laboratories);
- Training on “Conformity assessment -- General requirements for proficiency testing” according to the Standard ISO/IEC MKS EN 17043:2010; and
- Training on the Standard MKS EN ISO 9001.

In addition to training, as part of the Project activities, 7 short-term expert missions were carried out as well as 2 supervisions of surveillance assessments according to the standard MKS EN ISO/IEC 17025:2005, followed by a five day study visit to the Institute for Accreditation from Lithuania (LA), by 5 employees of the IARM.

Also, in 2012, the implementation of the Software was initiated for enforcement of accreditation procedures, procured with Budget co-financing under the Project.

The foreseen core aims of the projects such as the increase in the number of technical assessors, improvement of the management system documentation, procurement of data management software, international recognition of the testing and certification reports and implementation of the directives based on the the New, Global and Old Approach – increased number of notified conformity assessment bodies have all been successfully attained.

Through the ***IPA Regional Project***, the employees of the IARM attended the training for PT providers.

The Regional Project ***“Promotion of Regional Cooperation in Southeastern 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 PT schemes for laboratories according to the Standard MKS EN ISO/IEC 17043;
- Training for calibration laboratories (training seminar for assessors of calibration laboratories MKS EN ISO/IEC 17025:2005);
- Training on eco-management and audit schemes (EMAS);
- Training for PT providers;
- Training on the Standard ISO 15189 for medical laboratories;
- Training on chemical residues in food: technical aspects of accreditation (validation, verification, quality assurance) and
- Training on “Policy of the EA for conformity assessment schemes in accordance with EA 1/22”

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

- training for assessors of EA-MLA
- training of trainers on the Standard MKS EN ISO/IEC 17024:2012 and
- training of trainers on the Standard MKS EN ISO/IEC 17020:2012

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” for whose implementation the signing of the EA-MLA and ILAC-MRA Agreements played a pivotal role.

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 2012, 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).

On the basis of the foregoing, the IARM fully implemented all activities envisioned under this item of the Work Program of the IARM for 2012.

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.

2. Signing of the Agreement for mutual recognition of accreditation certificates

2.1. Signing of the Agreement for mutual recognition of accreditation certificates with the European cooperation for Accreditation (EA –MLA)

As stipulated in the Work Program of the IARM for 2012, the main aim was to sign the Agreement for mutual recognition of the accreditation certificates with the European cooperation for Accreditation (EA-MLA).

The procedure for signing of this Agreement in 2012 was made official through the recommendation provided by the EA assessment team for the signing of the Agreement for mutual recognition of accreditation certification with the European cooperation for Accreditation (EA-MLA). The meeting of the Multilateral Agreement Committee (EA-MAC) which took place on the 18th and 19th April 2012 in Copenhagen, Denmark, endorsed the signing of the EA-MLA Agreement with the IARM.

The official signing of the Agreement took place at the EA Annual Assembly meeting, on the 22-24th May 2012, in Madrid, Spain. The signing of this Agreement means that starting from April 2012, the issued certificates and reports by accredited Macedonian bodies (testing laboratories and calibration laboratories, inspection and certification bodies for products) shall be equally valid across the European market.

2.2. Signing of the Agreement for mutual recognition of accreditation certificates with the International (global) Laboratory Accreditation Cooperation (ILAC-MRA)

The signing of the Agreement with the European cooperation for Accreditation brought on the signing of the second important international document- Multilateral Agreement for recognition of accreditation in the areas of testing, calibration and inspection with the International Laboratory Accreditation for Cooperation - ILAC-MRA, which again is another achievement of the IARM in the international arena. The Agreement was officially signed within the ILAC's Annual Assembly meeting, held between the period of 16-26 October 2012, in Rio de Janeiro, Brazil, thereby achieving international recognition of reports from testing and calibration laboratories issued by the Macedonian accredited laboratories, as well as reports by the accredited inspection bodies.

The benefits of signing of both Agreements have already been felt by the national companies, since by the means of such agreements the trade barriers have been lessened and free movement of goods and services from Republic of Macedonia to international markets enabled. Namely, once tested/certified product or service from an accredited body in the country can be freely exported abroad, without being subject to repeated attestation.

The signing of the Agreements was accompanied by appropriate information and promotional activities by the IARM.

3. Organization of training

IARM in 2012 organized training for various target groups such as: the conformity assessment bodies and other economic operators, assessors (employees in the IARM and external).

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, individually organized training on such important issues on the following topic:

- Training on implementation of the Standard MKS EN ISO/IEC 17020:2006 for “bodies performing inspection and inspection methods for tachographs and taximeters”.

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 MKS EN ISO/IEC 17025:2006 and
- Training on amendments to the Standard MKS EN ISO/IEC 17020:2012.

The lecturers of the training were the staff of the IARM, and the target group were the employees in the accredited bodies (inspection bodies, testing and calibration laboratories), the staff of the institutions undergoing accreditation, as well as the leading and technical assessors.

All training sessions were organized in the Training Center of the IARM.

In accordance with the requirements of the Standard MKS EN ISO/IEC 17011, in support of the maintenance of the system for accreditation and upgrade of the capacities of the employees in the IARM, two training sessions for practical application of the requirements of the Standard were organized, in correlation with the work procedures of the IARM. The first training was carried out in March, whereas the second one in November 2012, which among other things was organized as a preparatory activity for the upcoming first regular supervision (October 2013) upon signing of the EA-MLA, to be performed by the EA assessment team.

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

The list of assessors of the IARM is composed of 63 assessors of which 16 are leading assessors, 33 technical assessors in various fields and 14 technical assessors in training, 6 candidates for assessors and 37 experts. Of the total number of leading assessors, 10 are regular employees of the IARM.

4. Promotion of the accreditation system

In 2012, the following promotional events were organized:

- On the 13th June 2012, the international Accreditation Day was commemorated. IARM organized a promotion on the occasion of awarding Certificates for accreditation to conformity assessment bodies accredited during 2011. The promotion was organized at the hotel Alexander Palace. This event was also used to officially announce the completion of the national IPA project “Technical assistance for capacity building of the Institute for Accreditation of the Republic of Macedonia (IARM)”. Mr. Thomas Facklam, the Chair of the European cooperation for Accreditation, also participated at this event. Corresponding to the commemoration of the

World Accreditation Day, the IARM issued a brochure entitled “Accreditation- support to safe food and clean drinking water”. The event received media coverage.

- In 2012, the IARM issued the regular “Annual Work Program of the IARM for the year 2011”.
- The IARM in cooperation with the Consumers’ Organization of Macedonia (COM), organized a campaign for promotion of the accreditation system of the Republic of Macedonia, for raising the awareness of the need and significance of accreditation, as well as the safety of products, with special emphasis on safety of lifts and their maintenance. As a part of the promotional campaign, panel discussions and debates were held in Stip, Bitola, Ohrid, Kocani, Tetovo and Skopje.

For the purposes of the campaign, two informative brochures were published entailing the following topics: “Accreditation – promoter of quality” and “Lifts, their maintenance and periodic checks, basic information and guidelines for legal entities and natural persons”; also, “Infotheca” aggregating all information as to the entire accreditation procedure and the benefits thereof. The Infotheca can be accessed on the website of the IARM and the COM.

- In cooperation with the Macedonian Chambers of Commerce, IARM organized a press conference in order to promote the signing of the Agreement for mutual recognition of accreditation results with the European cooperation for Accreditation, the EA-MLA.

- A presentation was delivered on the topic “Accreditation of food testing laboratories” at the Faculty of Agriculture and Food, within the International Symposium.

- Interview was also delivered on the “System of accreditation in the Republic of Macedonia, with special emphasis on accreditation in the health sector” for the “Pharmaceutical newsletter” a journal of the Pharmaceutical Chamber of the Republic of Macedonia.

- At the meeting of the Macedonian Association of Laboratories MAKLAB, the accreditation system and its significance for the laboratories were promoted. This activity, as well as all other forms of cooperation with MAKLAB is exercised via an already established manner of cooperation with this Association, in support of the promotion of accreditation and familiarization of the laboratories as to the need and importance of accreditation.

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. During 2012, the two bodies operating within IARM have held a total of 12 regular meetings each.

6. International activities

In 2012, 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 PECA/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.

During 2012, the procedure for signing of the Bilateral Cooperation Agreement with the Russian accreditation authority, as a national accreditation body of the Russian Federation was initiated. 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;
- Participation at the Regional Conference on Accreditation in Arandjelovac Serbia, organized by the accreditation authority of Serbia, attended by representatives from the accreditation bodies of Serbia, Montenegro, Kosovo, Albania, Croatia as well as representatives from the national and the regional IPA project; and
- Participation at the regular annual Meeting of the accreditation bodies from the region in Belgrade.

On the grounds of the foregoing, it can be concluded that the IARM has fully enforced all activities envisaged in the Work Program of the IARM for the year 2012, and achieved notable success by signing the two international Agreements with the European and International accreditation organizations – the EA-MLA and the ILAC-MRA.

Acting Director
Trpe Ristoski, PhD
