



**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 2011

Report on the implementation of the Work Program of the Institute for Accreditation of the Republic of Macedonia for 2011

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 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

The Parliament, at the session on the 11th April 2011, has adopted the Law amending the Law on Accreditation.

II. Implemented activities of the IARM in 2011

In accordance with the Work Program of the IARM for 2011, adopted by the Government of the Republic of Macedonia and published in the “Official Gazette of the Republic of Macedonia” No. 03/2011, the IARM has implemented the following activities:

1. Accreditation activities

a. Status of accredited bodies

So far, a total of 94 conformity assessment bodies have been accredited. Eleven of them have had their accreditation withdrawn.

In 2011, a total of 27 conformity assessment bodies have been *granted accreditation* as follows:

Type of body	Name of the Body	Date
Inspection body MKS EN ISO/IEC 17020	Iprom- Skopje	26.01.2011
Inspection body MKS EN ISO/IEC 17020	AM Cert	27.01.2011
Inspection body MKS EN ISO/IEC 17020	Taho Servis- Obleshevo	09.03.2011
Inspection body MKS EN ISO/IEC 17020	AMD Tahograph – Ohrid	28.03.2011
Inspection body MKS EN ISO/IEC 17020	Srna- SN- Skopje	28.03.2011
Inspection body MKS EN ISO/IEC 17020	Femili- TTV- Skopje	28.03.2011
Inspection body MKS EN ISO/IEC 17020	Tehnicki pregled- AMD- Tetovo	27.04.2011
Inspection body MKS EN ISO/IEC 17020	AMD Kiro Burnaz- Kumanovo	27.04.2011
Inspection body MKS EN ISO/IEC 17020	Avto Sigurnost- Strumica	11.05.2011
Inspection body MKS EN ISO/IEC 17020	Auto Meklaren	01.06.2011
Inspection body MKS EN ISO/IEC 17020	JP Vodovod- Skopje	01.06.2011
Inspection body MKS EN ISO/IEC 17020	Kinzle- Prilep	06.07.2011
Inspection body MKS EN ISO/IEC 17020	Pi- Kom Gostivar	06.07.2011
Inspection body MKS EN ISO/IEC 17020	AMD Gj.N usluga- Bitola	20.07.2011
Inspection body MKS EN ISO/IEC 17020	ASUC- Boro Petrushevski	20.07.2011
Inspection body MKS EN ISO/IEC 17020	Baleks- taho- Shtip	20.07.2011
Inspection body MKS EN ISO/IEC 17020	Sojuz na vozachi (Drivers Association)	17.08.2011
Inspection body MKS EN ISO/IEC 17020	PSS- tahographi	21.09.2011
Inspection body MKS EN ISO/IEC 17020	Bobo- Mag	21.09.2011
Testing laboratory MKS EN ISO/IEC 17025	Laboratory of the Sasa mine	23.02.2011
Testing laboratory MKS EN ISO/IEC 17025	JP Vodovod- Skopje Sanitary Control Center	01.03.2011
Testing laboratory MKS EN ISO/IEC 17025	MESSER - Tehnogas	22.03.2011
Testing laboratory MKS EN ISO/IEC 17025	Eko- Detekt	23.05.2011
Testing laboratory	Euromak Kontrol- Skopje	23.05.2011

MKS EN ISO/IEC 17025		
Testing laboratory MKS EN ISO/IEC 17025	Faculty of furniture design and technologies	12.07.2011
Testing laboratory MKS EN ISO/IEC 17025	GEING KiK	17.10.2011
Calibration laboratory MKS EN ISO/IEC 17025	JZU CJZ Veles	21.11.2011

In 2011, four conformity assessment bodies have been ***granted re-accreditation*** and three conformity assessment bodies have had their ***accreditation withdrawn***.

In 2011, the IARM has delivered 55 regular ***surveillances to accreditation bodies***.

The total number of assessment man/days in 2011 is 651, representing double the man/days in comparison to 2010. The majority of assessment man/days, more precisely 312.5 have been delivered by the leading assessors, a regular staff of the IARM, whereas 240.5 man/days have been delivered by external, national assessors and experts and 98 man/days by international assessors and experts.

b. Project activities

In 2011, the IARM has been engaged in the implementation of four international projects as follows:

Starting the 1st February 2011, the activities in the 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)”*** were officially initiated. The project is being implemented by the consortium composed of the “Federal Institute for Materials Research and Testing“ (BAM) from Germany and the Institute for Accreditation from Lithuania.

Within the Project, a total of 11 trainings were carried out as follows:

- Training on Standard ISO/IEC 19011, by adapting the Standard ISO/IEC 17011. Differences between horizontal and vertical audit and witnessing;
- Training for interpretation of the documents EA-2/17 “EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes“;
- Training on EU Directives;
- Training on notification procedures applied pursuant to EU requirements;
- Training on traceability and calculation of uncertainty of measurement in the area of chemistry and microbiology.
- Training on Standard ISO/IEC 17020:2004 “General criteria for the operation of various types of bodies performing inspection“ and elaboration of the document IAF/ILC A4.
- Training on Standard ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories”.
- Training on Standard EN 45011:2000 “General requirements for bodies operating product certification systems” and elaboration of the document IAF GD 5:2006
- Training on Standard ISO/IEC 17011:2004 “Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies” and

elaboration of document IAF/ILAC A3:05/2007 as well as remaining relevant EA documentation.

- Training on traceability and calculation of uncertainty of measurement in the area of calibration and mechanical measurements.
- Training on assessment and sampling the environment.

In addition to training, as part of the Project activities, 21 short-term expert missions of a total of 142 man/days have been carried out as well as a five day study visit to the German Accreditation Institute by 5 employees of the IARM followed by 5 supervisions of surveillance assessments according to the following standards: MKS EN ISO/IEC 17025:2005 (twice); MKS EN ISO/IEC 17020:2006; MKS EN 45011 and IAF GD5; MKS EN ISO/IEC 17021:2011.

Similarly, during 2011 an open procedure for public procurement has also been announced for procuring accreditation procedures enforcement software aided by Budget co-financing within the Project.

Through the **IPA Regional Project**, the employees in the IARM participated at the following trainings:

- Harmonization of requirements for assessors and technical experts of national accreditation bodies of Western Balkan countries, Zagreb, Croatia
- Meeting of the Regional Network on Issues related to Accreditation, Istanbul, Turkey.

In addition to trainings, a meeting was organized for compiling a Regional List of Assessors in accordance with the EA rules. The meeting took place in Budapest, Hungary.

The activities envisaged with the project of the **German Society for Technical Cooperation (GTZ)** have been directed towards promotion of the IARM and significance of accreditation on a national level. Under the Project, the IARM organized a Regional Accreditation Conference on the 28th and 29th September, 2011 in Ohrid, Republic of Macedonia. The Conference was attended by representatives of the accreditation authorities of Serbia, Montenegro, Kosovo, Albania, and Croatia as well as representatives from the national and regional IPA project.

The Regional Project “Promotion of Regional Cooperation in Southeastern Europe in the Field of Quality Infrastructure” directed towards the accreditation authorities of Macedonia, Serbia, Albania, Montenegro, Bosnia and Herzegovina and Kosovo, financed by the **German Institute for Metrology**, encompassed the following activities participated by the IARM’s staff:

- Workshop on the accreditation process, Ankara, Turkey;
- Workshop on the document EA 2/17 and the New Approach Directives, Athens, Greece;
- Observation during surveillance visit of medical laboratory accredited following the Standard EN ISO/IEC 15189, Athens, Greece;
- Training for assessors “Validation of analytical methods in chemical laboratories“, Belgrade, Serbia;
- Training for assessors “Assessment of traceability of measurements in testing laboratories“, Skopje, Macedonia;

- Round table on harmonization of accreditation procedures among the countries–participants in the Project, in accordance with the rules of the European cooperation for Accreditation, Athens, Greece

c. Cooperation with state administration 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.

We would like to place particular emphasis on the participation of the IARM in the activities of the project of the Government of the Republic of Macedonia “Macedonian Sun” for which project the signing of the Agreement for mutual recognition of the accreditation certificates, MLA-Multilateral Agreement between the Institute for Accreditation of the Republic of Macedonia (IARM) and the European cooperation for Accreditation, plays a pivotal role.

Similarly, we would like to stress the participation of the IARM in the activities of the Government.

Also, within the activities of the Market Monitoring Committee, the IARM participated by organizing three training sessions for the inspectors of the State Market Inspectorate, for representatives of the Customs Administration, as well as for representatives of the economic chambers in the Republic of Macedonia.

In 2011, IARM took an active role in the work of the Technical Committees in the Institute for Standardization of the Republic of Macedonia.

d. Human resources

The Personnel Evaluation Committee performed a revision on the files of all members of the list of assessors and experts and continuously upgrades 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 previously stated, the IARM fully implemented all activities envisioned under this item of the Work Program of the IARM for 2011.

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

During 2011, the Council and Director of the IARM fully revised the documents of the quality management system. The new document issues contain amendments pursuant to the new Law on Accreditation, the Statute of the IARM and above all, they are in accordance with the recommendations of the EA assessment team, set forth in the reports of the preliminary assessment and peer evaluation for the signing of the Agreement for mutual recognition of accreditation certification with the European cooperation for Accreditation (EA-MLA).

By amending all documents of the quality management system, all remarks identified in the Preliminary Assessment Report were actually removed, as a part of the procedure for signing of the Agreement. Namely, the preliminary visit of the EA assessment team, took place in the period between the 7th and 11th December 2009. Upon the completion of the preliminary

assessment, the team submitted a Report enclosing the identified remarks. The remarks of the Report were removed, and the undertaken corrective action accepted by the team. The peer evaluation visit took place in the period between the 23rd and 29th October 2011. Also, the team prepared a Report providing for identified 13 remarks as regards to the operation of the IARM. These remarks were fully eliminated by the IARM concluding 30th December 2011, and the IARM has officially been granted a recommendation by the EA assessment team for signing of the Agreement for mutual recognition of the accreditation certificates with the European cooperation for Accreditation (EA-MLA).

As a result of all previously mentioned activities, the IARM expects placement on the agenda for the upcoming meeting of the Multilateral Agreement Committee (EA-MAC) which is to take place on the 18th and 19th April 2012 in Copenhagen, Denmark, thus hosting the Agreement endorsement vote.

The signing of this Agreement for mutual recognition of accreditation certificates with the European cooperation for Accreditation (EA-MLA), or the international recognition of certificates issued by the IARM has multiple importance for the Macedonian economy since this Agreement shall assign the Macedonian companies accredited by the IARM equal status and treatment as their competitors in Europe and globally as well; and all Macedonian products tested by the bodies accredited by the IARM shall be directly marketable to international markets without additional examination.

Similarly, the signing of this Agreement shall be considered key to the implementation of several projects by the Government of Republic of Macedonia, among which we highlight the project entitled “Macedonian Sun”.

Organization of training

IARM in 2011 organized around 20 training sessions targeted to various groups such as: the conformity assessment bodies and other economic operators, assessors (IARM’s employees and external ones); members of the Council of the IARM, inspectors from the State Market Inspectorate, representatives of the Customs Administration etc.

Majority of the above-stated trainings were organized within the national IPA 2008 Project, as well as under the project “Promotion of Regional Cooperation in South-East Europe in the Area of Quality Infrastructure“, financed by the German Metrology Institute. We would like to particularly emphasize the training sessions for leading assessors and assessors, in order to eliminate the remarks in the Report of the EA assessment team for signing of the Agreement for mutual recognition of results with the European cooperation for Accreditation (EA-MLA).

All trainings were organized in the Training Center of the IARM that during 2011 was fully reconstructed.

During the 2011, the employees of the IARM who actively participated in the accreditation procedures, attended to an average of 8 days of training.

As a result of all previously mentioned trainings, the IARM has significantly raised institutional strengthening through education of the regular employees as well as of the international associates.

The personnel in the IARM is composed of 16 regular employees, 31 expert, 6 candidates for assessors and 60 assessors of which 16 leading, 21 technical assessors in various areas and 23 technical assessors under training.

3. Promoting the accreditation system

In 2011 the following promotional events took place:

- 9th June 2011 commemorating the International Accreditation Day, IARM organized a promotion on the occasion of awarding Certificates for accreditation to conformity assessment bodies accredited during 2010. The promotion was held in hotel “Alexander Palace”. This event was also used to promote the national IPA project “*Technical assistance for capacity building of the Institute for Accreditation of the Republic of Macedonia (IARM)*”.
- In 2011 the IARM issued the “Annual Report on the Operation of the IARM for 2010”.
- IARM participated in several activities organized by the Ministry of Economy and the Market Monitoring Committee.

3. 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 3 members. During 2011, the two bodies operating within IARM have held a total of 12 regular meetings each. The remuneration of the body members is conducted according to a held meeting (for not more than 12 annual meetings) and according to attendance of members.

4. International activities

In 2011, 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, Mutual Recognition of Accreditation Certificates 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 participates in the work of the ILAC (International Laboratory Accreditation Cooperation), in which IARM has the status of an associate member.

In August 2011 signed an international agreement for ***bilateral cooperation*** with the Institute for Accreditation of Moldavia. With all regional accreditation authorities, the IARM has already signed bilateral agreements.

Within the previously signed bilateral agreements, the IARM delivered the following activities:

- Participation in joint trainings
- Shared activities under the regional IPA project

- Exchange of experts with the accreditation bodies from Serbia, Croatia and Bulgaria.

5. Management and current operation of the IARM

Taking into account the fact that the four-year mandate of the members of the Council of the IARM had come to an end in October 2010, on the 13th April 2011, the Government of the Republic of Macedonia following a Decision No. 22-1247/2 nominated the members of the new Council of the IARM.

Similarly, in November 2011, the mandate of the Director of the IARM was also over, and the public notice for election of a Director of the IARM has been announced at the end of 2011. The procedure is ongoing.

For a more efficient operation of the IARM, in 2011, a procurement of cashiers/treasurers software has been concluded as well as the renovation of the Training Center of the IARM.

On the basis of the afore-stated, it can be ascertained that the IARM has fully implemented all activities envisaged in the Work Program of the IARM for 2011.

**Acting Director
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