

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

**REPORT on  
the performed annual programme on the operations of  
IARNM for 2018**

# **Report on the performed annual programme on the operations of the Institute for Accreditation of Republic of Macedonia for 2018**

## **I. Introduction**

According to the Law on Accreditation, ("Official Gazette of the Republic of Macedonia", No.120/09, 53/11, 41/14, 53/16 and 83/18), the Institute for Accreditation of the Republic of Macedonia (hereinafter referred to as: 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 awarded 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 legal framework of the IARM is defined by: the Law on Accreditation; the Statute of IARM; the acts of the Council; the acts of the IARM's director and other records.

Bodies of the IARM are as follows:

1. Council
2. Director and
3. Supervisory Board for Material and Financial Affairs.

Within the process of accreditation, 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. Activities completed by IARM in 2018**

According to the Annual Programme on the Operations of IARM for 2018, adopted by the Government of the Republic of Macedonia and published in the "Official Gazette of Republic of Macedonia" no. 21/2018, the Institute has completed the following activities:

### **1. Accreditation activities**

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

By the end of 2018, a total of 221 conformity assessment bodies were accredited, of which 177 accreditations were active, and 44 accreditations were withdrawn/expired/suspended upon request of the bodies or ex officio.

In 2018, a total of 10 new conformity assessment bodies were accredited, as follows: 3 testing laboratories, 3 product certification bodies and 4 inspection bodies.

In 2018, about twenty conformity assessment bodies were granted reaccreditation, whereas among the other conformity assessment bodies IARM conducted regular surveillance within which cross-border surveillance activities were performed.

Based on the previous preparations, the Institute commenced assessments as per the new standard EN ISO 17025:2017.

The accredited conformity assessment bodies also include accredited laboratories in higher education institutions furnished by the Government of Republic of Macedonia, and medical laboratories designated by the Ministry of Health, whose accreditation was envisaged in this government project.

**Disbursed funds..... 11.391.417,00 denars**

**2. Maintenance of the status of a signatory of the Agreement for mutual recognition of accreditation certificates with the European Cooperation for Accreditation (EA-MLA) and expansion of the scope to a new area**

In 2018, the positive Report on the second regular supervision was approved, following the signing of the Agreement for mutual recognition of accreditation certificates with the European Cooperation for Accreditation.

Namely, as per the Rules and the Operational Programme of the European Cooperation for Accreditation (EA), IARM's operations in the field of accreditation, the established quality management system, and the overall organizational, structural, and management operation and governance of IARM were subject to regular surveillance assessment for the signing of the Agreement and the announced expansion with a new area. The final report from the assessment, together with the positive recommendation for maintenance of the status as signatory of the Agreement and expansion of the scope of the same with a new area – certification of management systems, was adopted by the EA MAC Committee on the fall meeting that took place in October 2018.

The maintenance of the importance of the signed international agreement for mutual recognition of the results from the accreditations, concluded with EA, is a prerequisite for maintenance of the international agreements for recognition of the results from accreditations concluded with: International Laboratory Accreditation Cooperation – Mutual Recognition Arrangement (ILAC-MRA) and the International Accreditation Forum – Mutual Recognition Arrangement (IAF-MRA).

**Disbursed funds..... 959.247,00 denars**

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

**a.** In accordance with the Annual Training Plan of IARM for 2018 and the internal training procedures of IARM, IARM organized the following trainings:

- Training for EN ISO/IEC 17011:2017
- Training for leading and technical assessors according to the standard MKC EN ISO/IEC 17025:2018
- Training for assessors and experts of IARM
- Training for assessors for application of the document of ILAC-P14 and training on the manner of stating the scope in the application for accreditation, the attachment to the certificate and other documents
- Training for the requirements of the standard EN ISO/IEC 17021-1:2015 and the valid guidelines
- Training for the employees in IARM for application of DMS software of IARM.

As a result of the completed trainings, IARM upgraded its institutional capacities through education of both regular employees and external associates.

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

In 2018, IARM participated in the implementation of the following international projects:

##### **❖ PTB activities**

Via the PTB project "Promotion of regional cooperation in South Eastern Europe in the field of infrastructure for quality in the organic production", it participated at the:

- Workshop "Inspections for risk-based animal and vegetable production"
- Workshop "Inspections for risk-based beekeeping"

##### **❖ Project for quality infrastructure of the countries in Western Balkans**

- Workshop for application of the new version of EN ISO/IEC 17025:2017
- Training for EN ISO/IEC 17011:2017

#### **c. Human resources**

The care for competent human resources as a prerequisite for quality implementation of the accreditation procedures is under the competence of the Personnel Evaluation Committee. In addition to the regular activities for updating the files of all members on the list of assessors and experts, the Personnel Evaluation Committee followed the implementation of the Plan and Programme for training assessors for the purpose of updating the list of IARM's assessors and experts, in accordance with the procedures of the European Cooperation for Accreditation (EA).

As a result of the trainings completed, the competence of domestic assessors and experts from many areas is maintained and strengthened, since while performing the assessment, many domestic assessors/experts are engaged by the assessment teams. This was also a priority objective of IARM in all these past years of operation. The engagement of expert assessors from the region is done depending on the needs, where conflict of interest between the assessor and the conformity assessment body may exist or when developing new accreditation schemes.

Hence, it follows that the Institute has fully implemented all activities envisaged under this item in the Annual Programme on the Operations of IARM for 2018.

IARM's staff comprises 16 full-time employees, of whom 14 have status of administrative officers. According to the Law on Administrative Officers, evaluation process of their work was also performed.

Pursuant to the needs of IARM and the constant call for assessors, published on the IARM's website in 2018, the number of applications filed for assessors has visibly increased. The list of assessors of IARM consists of: 19 lead assessors and 2 lead assessors-in training, 64 technical assessors, 7 assessors-in training and 39 experts. The Plan for supervision of assessors was conducted according to the planned dynamics.

Of the total number of lead assessors, 8 are full-time employees of IARM.

**Disbursed funds..... 7.572.813,00 denars**

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

In 2018, IARM participated in the work of the Technical Committees within the Institute for Standardization of the Republic of Macedonia.

In 2018, IARM employees regularly participated in the working groups of the Ministry of Economy, and cooperated with the Ministry of Information Society and Administration.

**Disbursed funds.....0,00 denars**

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

In 2018, the following promotional events took place:

- Under the slogan "Accreditation: Delivering a safer world" on November 30<sup>th</sup>, the Institute for Accreditation of Republic of Macedonia celebrated the World Accreditation Day with a corresponding event.

The event was attended by numerous guests, representatives of the Government of Republic of Macedonia, the public sector, scientific and educational institutions, health care facilities, associates, representatives of conformity assessment bodies, and journalists.

- As part of the World Accreditation Day celebration, IARM issued a corresponding brochure under the slogan "Accreditation: Delivering a safer world". During the event, IARM organized a ceremony for awarding accreditation certificates to the conformity assessment bodies accredited during the 2017/18 period, and also promoted the Annual Bulletin on the operations of IARM for 2017. The event took place at Hotel Continental in Skopje. The event was covered by respective media reports.
- In 2018, IARM issued the regular "Annual Report on the Operations of IARM for 2017".
- IARM issued two brochures on the following topics: "ILAK-Mutual Recognition Arrangement" and "Accreditation: Short guideline for the Government and regulators".

**Disbursed funds..... 944.000,00 denars**

## **6. Operations of IARM's Council and Supervisory Board for Material and Financial Affairs of IARM**

In 2018, IARM's Council was completed in terms of the number of members, and the four representatives of the government are still holding a status of acting members. The IARM Council held 8 regular sessions.

The Supervisory Board for Material and Financial Affairs of IARM began their operation following the appointment of two members out of total three members in April 2018, and then their composition was completed with the appointment of one additional member. The Supervisory Board for Material and Financial Affairs held 11 regular sessions.

**Disbursed funds..... 988.322,00 denars**

## **7. International activities**

In 2018, IARM had many international activities:

- IARM is actively monitoring and participating in the work of the European Cooperation for Accreditation. IARM's employees participated in the work of the Committees of the European Cooperation for Accreditation (EA MAC, Laboratory Committee, Inspection Bodies Committee, Certification Bodies Committee, Horizontal harmonization Committee, Committee for communication and publication as well as in the working groups operating within different committees).

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

- IARM has duly paid its annual membership fee for 2018 to the European and World organizations for accreditation, as well as the fees to the International Accreditation Forum.

- IARM took part in the work of the Subcommittee on Trade, Industry, Customs and Taxation, as well as in National programme for adoption of the acquis

- An assessor from IARM took part in peer evaluations organized by EA;

With the rest of regional accreditation institutes, with whom IARM has already signed bilateral agreements, the cooperation is continuous and ongoing. Within these agreements, IARM implemented 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;
- Participation at the regular Annual Meeting of the accreditation bodies from the region in Belgrade;
- Participation at the international event "Week of quality 2018" in Belgrade;
- Participation on the international conference "Competence of laboratories" in organization of KROLAB, Croatia

- Participation on congress of assessors, in organization of the Russian Federal Service for accreditation

**Disbursed funds..... 1.472.785,00 denars**

## **8. Management and current operation of IARNM**

The following was regularly maintained and upgraded: technical resources necessary for daily performance of work duties, as well as other ongoing activities aimed at providing the appropriate conditions for performing the said duties.

In accordance with the requirements of the new edition of the international standard EN ISO / IEC 17011: 2017, which is the basic standard for the IARNM operation, during the transition period, for the start of its implementation, the employees attended trainings, followed by internal preparations for audit and harmonization of documents from the quality management system.

**Disbursed funds..... 1.319.494,00 denars**

## **III. Concluding observations**

Based on afore mentioned, it may be concluded that IARNM has fully implemented the activities envisaged in the Annual Programme on the Operations of IARM for 2018.

The successful implementation of planned activities is measurable through the increased number of accreditation certifications awarded, through maintenance of current accreditations, strengthened competences of IARNM's employees and external associates, maintenance and upgrading of an effective quality management system, maintenance of the international reputation and status of IARM (by maintaining the international agreements valid: EA-MLA, ILAC-MRA, and IAF-MLA agreement), verified by the successfully completed second regular surveillance, by maintenance of the bilateral cooperation with other national accreditation bodies, by adequate promotion of the accreditation system, by cross-border accreditation activities, and by concurrent active domestic operations.

Acting Manager  
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