



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

**WORK PROGRAMME
of the Institute for Accreditation of the
Republic of North Macedonia
for the year 2022**

Act: PR 2022

Pursuant to Article 5 Paragraph (2) of the Law on Accreditation (“Official Gazette of the Republic of Macedonia”, No. 120/09, 53/11, 41/14, 53/16, and 83/18), the Government of the Republic of North Macedonia at its session held on _____ 2022 adopted the following

Work Programme of the Institute for Accreditation of the Republic of North Macedonia for the year 2022

I. Introduction

Pursuant to the Law on Accreditation, the Institute for Accreditation of the Republic of North Macedonia (hereinafter: IARNM) is a public institution that performs the activities and tasks as a single national accreditation body, in line with the prescribed accreditation procedure based on this and other laws and supervises meeting the accreditation requirements.

Accreditation is a procedure for formal recognition of the capacity to perform certain activities in the sense that a certain body for conformity assessment fulfills the requirements stipulated by national, European, and international standards, relevant legislation, IARNM procedures, as well as the recommendations of European and global accreditation organization. Having in mind its role as a tool of the regulators and the state, in certain areas accreditation is prescribed as a legal requirement that a certain entity must meet if its operations require a specific authorization issued by a competent state body.

The main areas in which accreditation procedures are performed are:

- testing and calibration laboratories,
- medical laboratories,
- bodies that perform certification of products, processes, and services,
- bodies that perform certification of management systems and
- inspection bodies.

Accreditation is an internationally recognized tool that indirectly ensures and guarantees the safety and quality of products and services, free development of international trade, reduces costs and operational errors, at the expense of increasing efficiency and economy in the use of material and human resources.

Accreditation provides for the facilitation of world trade. This is because its primary significance or benefit lies in the fact that once examined certified products and services under the accreditation sign, do not need to be re-examined. Taking into account the fact that IARNM is a signatory to three important international agreements that provide this benefit, the same also applies to domestic products and services when placed on the market in and out of the country.

Namely, IARNM, as a full member of the European and World Accreditation Organizations, is a signatory of the international Agreements for mutual recognition of the accreditation certificates, namely:

- with the European Accreditation Organization (EA), it is a signatory to EA-MLA (Multilateral Agreement – MLA¹),
- with the International (World) Organization for accreditation of laboratories, inspection bodies, and organizers of proficiency testing (ILAC), it is a signatory to ILAC-MRA (Mutual Recognition Arrangement - MRA²) and
- with the International Accreditation Forum (IAF), it is a signatory to IAF-MLA Multilateral Agreement – MLA³) for accepting certificates and reports issued by accredited conformity assessment bodies worldwide.

By signing these Agreements, IARNM opened the doors for domestic products and services on the European and global market, in accordance with the principle “once accredited, accepted everywhere”.

Namely, the main benefit of the Agreements is that the documents issued by the Macedonian accredited conformity assessment bodies, in accordance with the standards MKC EN ISO/IEC 17025 for testing and calibration laboratories, MKC EN ISO/IEC 17020 for inspection bodies, MKC EN ISO 15189 for medical laboratories and MKC EN ISO/IEC 17065 for certification bodies for products, processes and services and MKC EN ISO/IEC 17021-1 for certification bodies for management systems, are recognized at European and global level.

The successful realization of the key determinations of IARNM at the international level so far is only an additional incentive, but also an obligation to fulfill the strategic interest and vision of IARNM in order to maintain and strengthen the status of a full member in international accreditation organizations.

II. Objectives of the IARNM Work Programme for the year 2022

It is the strategic interest and goal of IARNM to continually maintain and strengthen the accreditation system, which will provide confidence in the capacity of the conformity assessment bodies (certification bodies, testing and calibration laboratories, medical laboratories, and their inspection bodies) and also ensure free trade in domestic products and services in European and global markets.

Accreditation, both globally and in the Republic of North Macedonia, plays an important role in strengthening the internal market, and the quality and security of life and its primary role lies in the development of the domestic economy and its integration worldwide. However, for the Republic of North Macedonia, it is a particularly important instrument as a support for its integration into the European Union.

¹ EA-MLA is an agreement signed between the accreditation bodies, EA members, for the recognition of equality and confidentiality, and thus the acceptance of accredited certification, inspection, calibration certificates, and test reports throughout Europe.

² ILAC-MRA is an agreement signed between accreditation bodies, and ILAC members, for the recognition of equality and confidentiality, and thus the acceptance of accredited inspection certificates and test reports worldwide.

³ IAF-MLA is an agreement signed between accreditation bodies IAF members, for the recognition of equality and confidentiality, and thus the acceptance of accredited certificates issued by accredited certification bodies for products and management systems worldwide.

Taking into consideration the benefits from the realization of the previously projected plans and objectives of IARNM, which stand as a recognition of the successful performance of the accreditation activity, as well as the potentials that arise from them, their multifold significance should also be considered.

Hence, the main activities of IARNM in 2022 shall focus on maintaining and upgrading the quality management system in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018, as a basic precondition for implementing the Agreements.

- Primary objective for Programme realization:

Maintenance and upgrade of the quality management system of IARNM in accordance with the requirements of the new edition of the standard MKC EN ISO/IEC 17011:2018, as the basic and only standard according to which IARNM operates and conducts its accreditation procedures.

The sustainability, functionality, and effectiveness of the system have been positively assessed by the EA assessment team as part of the newly conducted re-evaluation assessment.

- The specific objectives for Programme realization are as follows:

- increasing the number of bodies accredited by IARNM,
- institutional strengthening through new personnel and organizational solutions and coordination of accreditation activities by increasing the number of technical assessors and experts and upgrading the competencies of assessors and IARNM employees,
- continuous commitment to facilitate global trade by accepting the results of accredited conformity assessment bodies,
- promoting the services of the conformity assessment bodies accredited by IARNM,
- digitalization of the work process in IARNM,
- strengthening cooperation and providing technical support to the ministries and other institutions for any issues related to the accreditation procedures,
- active cooperation with European and international accreditation organizations,
- ongoing activities to gain more trust from stakeholders,
- upgrading the already established cooperation with the Chambers of Commerce in the Republic of North Macedonia, the Consumers' Organization of the Republic of North Macedonia, and the economic operators,
- deepening and expanding the cooperation with the national accreditation bodies from the region, Europe, and the world, and
- participation in the realization of international projects.

The realization of the Programme goals will be carried out with the funds provided in the Budget of the Republic of North Macedonia for 2022, as well as through participation in projects such as TAIEX – an Instrument of the European Commission, PTB, and others.

III. Projected activities for Programme realization

In the Budget of the Republic of North Macedonia for 2022, section 10001 - Ministry of Economy, Subprogramme 51 - IARNM, for the categories 40 - Wages and allowances, 42 – Goods and services, 46 - Subsidies and transfers, and 48 - Capital expenditures, there are financial resources planned in the amount of MKD 9,050,000.00 on account 637/603, and MKD 34,700,000.00 on account 631 or a total of MKD 43,750,000.00.

- About 20% of the funds are intended for salaries of employees from the Budget of the Republic of North Macedonia - account 637/603 IARNM.

- About 59% are intended for goods and services from accounts 637/603 and 631 IARNM.
- About 3% of the approved funds are intended for subsidies and transfers (for retirement severance pay, organization of the event World Accreditation Day)
- About 18% of the funds are intended for capital expenditures.

Institute for Accreditation of the Republic of North Macedonia

Category Item	Description	Budget 2022 (in 000 MKD)		Total expenditures
		637/603	631	
	Expenditures	9,050	34,700	43,750
40	Salaries and allowances	8,700		8,700
401	Basic salaries	6,270		6,270
402	Social security contributions	2,430		2,430
42	Goods and services	350	25,450	25,800
420	Travel and daily expenses	50	2,000	2,050
421	Utilities, heating, communication, transport	50	2,600	2,650
423	Materials and small inventory	50	1,500	1,550
424	Repairs and ongoing maintenance	100	2,500	2,600
425	Contracted services	100	12,500	12,600
426	Other current expenses		3,150	3,150
427	Temporary employment		1,200	1,200
46	Subsidies and transfers		1,200	1,200
463	Various transfers to nongovernmental organizations		1,200	1,200
48	Capital expenditures		8,050	8,050
480	Purchase of equipment and machinery		3,100	3,100
481	Construction buildings		700	700
485	Investment and non-financial assets		4,250	4,250

To review and maintain the efficiency and upgrade the established national accreditation system in accordance with the Law on Accreditation, standard MKC EN ISO/IEC 17011:2018, the rules of the European Accreditation Organization, the World Organization for Laboratory Accreditation, and the International Accreditation Forum (EA, ILAC, and IAF) and the internal documents of IARNM, it is necessary to implement the following activities:

1. Accreditation activities

In the official register of IARNM at the moment of preparation of this Programme, there are 201 active accredited bodies for conformity assessment, and procedures are underway for new accreditation applications. In 2022, regular inspections of the already accredited bodies will be performed, and at the same time, IARNM will decide upon newly submitted applications for accreditation, on the basis of which it expects an increase in the number of accredited bodies for conformity assessment.

In accordance with the Law on Accreditation, as well as the obligations arising from the signed international agreements, IARNM will continuously maintain and improve the overall accreditation system. Within the development activities, IARNM plans to develop new schemes and areas for accreditation, in accordance with the specific needs of the Republic of North Macedonia and the needs of clients. The development of new schemes and areas will take place upon request, in cooperation with stakeholders, assisted by the work of Technical Committees. At the time of preparation of this Programme, there was already an announcement for submitting a request for the development of an accreditation scheme for organizers of training schemes (RT providers).

Also, the activities for performing accreditation activities abroad will continue in the course of 2022, in line with the rules for cross-border accreditation.

Required funds..... 20,615,000.00 MKD

2. Verification of the Report from the third regular re-evaluation for maintaining the signatory status of the Agreement on mutual recognition of accreditation certificates with the European Accreditation Organization (EA-MLA)

Pursuant to the rules, plans, and work program of the European Accreditation Organization (EA), the third regular re-evaluation (supervision) for maintaining the signatory status of the Agreement on mutual recognition of accreditation certificates with the European Accreditation Organization (EA-MLA) was realized in the period from 29 November to 03 December 2021. The assessment included the overall assessment of the accreditation system, as well as the overall material and human resources available to the Institute.

In the forthcoming period, joint activities will follow undertaken by IARNM and the EA working groups for verification of the Report from the re-evaluation.

The maintenance of the Agreement through the presentation and defense of the established accreditation system and the fulfillment of the obligations arising from it through various activities is essential for the work of IARNM, the Macedonian economy, and for the state overall. At the same time, its maintenance is a precondition for maintaining the ILAK-MRA and IAF-MLA agreements in force.

Required funds 300,000.00 MKD

3. Training organization

Maintaining and upgrading the competence of both the employed assessors and the external persons - assessors and experts of IARNM is essential, but also a primary obligation that arises for IARNM from international agreements, as well as the obligations arising from the last re-evaluation by EA, as it is a basic precondition for quality and proper performance of accreditation procedures.

At the time of preparation of this Programme, the List of Active Assessors and Experts consists of 29 Lead Assessors, 96 Technical Assessors и 68 Experts. Eight of the lead assessors are from the IARNM staff, and the rest are external collaborators. In addition to assessors and experts from the Republic of North Macedonia, the list contains assessors and experts from other accreditation bodies, who are members of EA or with whom IARNM has signed a cooperation agreement. Namely, in order to meet the requirements of the accreditation standards, as well as to respond to the manifested needs for accreditation, technical assessors and experts from abroad are engaged in the accreditation procedures. The percentage of their engagement is decreasing on

yearly basis, since IARNM continuously strives to increase the number of competent domestic assessors and experts, in order to increase their engagement in the accreditation procedures.

Hence, in 2022, an account will be taken to strengthen the pool of assessors by ensuring participation in training, seminars, and workshops with the participation of candidates for assessors and technical assessors and training with involvement in supervised assessments.

In the course of 2022, IARNM plans to organize or ensure participation in the following training/workshops:

- Training for the employees and the members of the IARNM Council for the requirements of the standard MKC EN ISO/IEC 17011 - General requirements for the accreditation bodies that accredit the conformity assessment bodies, standard according to which IARNM operates (obligatory, for maintenance of the accreditation system),
- Training for the requirements of the standard EN ISO/IEC 17011:2017 (Impact of the pandemic COVID 19, exchange of experiences),
- Training for the requirements of the standard EN ISO/IEC 17011:2017 requirements for PT schemes-exchange of experiences),
- Training for medical laboratories (harmonization of assessors),
- Training for new and revised requirements of the European Regulation 848/2018 (Organic production),
- Training on quality of agricultural products (PDO, PGI, and TSI),
- Training for flexible accreditation scope,
- Training for the standard 17025:2017 in specific areas (biochemical and microbiological food testing),
- Evaluation training for giving a statement of conformity in laboratory reports/certificates,
- Training for evaluation of laboratories that perform internal calibration,
- Training for specific general requirements for the competence of providers for competency schemes according to the standard 17043,
- Measures for measurable traceability,
- Training for accreditation of validation and verification bodies (ISO 14065 + ISO/IEC 17029- Greenhouse gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of approval/Conformity assessment - General principles and requirements for validation and verification bodies),
- Training in a forensic and clinical autopsy,
- Accreditation training for the purposes of notification/approval/authorization in the field of Regulation (EC) 305/2011 (CPR - Construction Products),
- Accreditation training for notification/authorization in relation to Directive 2010/35/EU (TPED-Transportable pressure equipment) additionally ADR/ADN/RID,
- Training for accreditation of certification bodies for management systems that certify ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes,
- Training for harmonization of lead and technical assessors for internal rules and procedures in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018,
- Training for EA assessors,
- Training organized by the Committees at EA,
- Training for the standard 17020:2012,
- Training on biobanks for the requirements of the standard ISO 20387:2018,
- Training within the Eye Tonometry Project at the Bureau of Metrology (the project started in September 2021) and

- Training for documents from European and international accreditation organizations.

Training will be organized in line with the planned project activities and the training plan, the manifested needs, and the current transition periods of the international standards and will be attended by the employees of IARNM as well as the stakeholders, assessors, and experts.

Part of the training is planned to be organized by IARNM, and part within project activities, EA, and in cooperation with other accreditation bodies.

Also, the Annual Training Plan for the IARNM employees will involve generic and specialized training in accordance with the legal requirements for upgrading the professionalism and competence of the administrative employees.

Required funds 2,500,000.00 MKD

- **Human resources**

The Institute for Accreditation of the Republic of North Macedonia regularly employs a total of 15 people.

In accordance with the requirements of the standard 17011:2018 and the rules of the European and international accreditation organizations, the Institute needs, but also has an obligation to provide or have adequate staff capacity of professional and competent persons. Hence, in the forthcoming year, it is mandatory to realize employment of a large number of executors and promotions, in order to provide optimal human resources as a basic requirement of the rules for the organizational and functional set-up of any national accreditation body, which will be subject to evaluation within the forthcoming regular supervisory assessment by the EA and a key factor in maintaining the status of a signatory to international Agreements. Work funds provide finances for salaries, as well as other allowances for other employment rights.

Required funds 9,950,000.00 MKD

4. Cooperation with state authorities

IARNM will continue with activities that deepen the active cooperation with the state bodies through participation in the work of several working groups established by the Government of the Republic of North Macedonia, the Ministry of Economy, the Ministry of Environment and Physical Planning, the Ministry of Agriculture, The Bureau of Metrology, as well as other line ministries and state bodies.

Moreover, IARNM will pursue activities within the Committee for Market Surveillance and Cooperation with the Chambers of Commerce in the Republic of North Macedonia, as well as participate in the work of the Technical Committees at the Institute for Standardization of the Republic of North Macedonia.

Required funds..... 150,000.00 MKD

5. Conducting internal inspections

Pursuant to the requirements of the standard MKC EN ISO/IEC 17011:2018, the realization of the regular internal inspection of the employees in IARNM is a mandatory obligation and need in order to maintain and enhance the quality management system in IARNM. The internal

inspection in 2022 will be conducted in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018.

6. Management re-evaluation

Pursuant to the Quality Policy and Work Procedures of IARNM and the requirements of MKC EN ISO/IEC 17011:2018, re-evaluation of the IARNM management (Director, President of the Council, quality manager, heads of departments and sectors) is realized once a year).

The purpose of the re-evaluation is to define and redefine the policies and objectives of IARNM and examine the effectiveness of the IARNM's quality management system through the analysis of documents, reports, complaints, objections, remarks, and inconsistencies.

7. Promotion of the Accreditation System

IARNM strives to continuously promote the need for accredited and authorized bodies based in the Republic of North Macedonia. The promotion of the accreditation system is crucial for raising awareness of the importance and role of accreditation in everyday life and for the economy.

Hence, it is necessary to inform the public about the manner of application and the manner of obtaining the status of an accredited body, i.e. bringing the interested parties closer to the conditions for accreditation, as well as promoting its benefits. Also, IARNM plans to organize new promotional events by which all stakeholders will be introduced to the benefits and usefulness of signing international agreements EA-MLA, ILAC-MRA, IAF-MLA, and the use of signs proving their signature status.

As part of the promotion of the accreditation system, the following activities are planned:

- Preparation and publication of promotional and educational material in the field of accreditation, on topics recommended by European and global accreditation organizations,
- Media promotion of accreditation,
- Issuing the Annual Report on the work of IARNM for 2022,
- Promotion for awarding certificates to accredited bodies, on the occasion of June 9, "International Accreditation Day",
- Cooperation with the Consumer Organization in the Republic of North Macedonia,
- Cooperation with the Chambers of Commerce in the Republic of North Macedonia,
- Organizing and/or participating in conferences or other types of gatherings on topics relevant to the role of accreditation,
- Development, maintenance, and upgrade of the official website of IARNM, as well as
- Participation in the International Conference on Quality and Competence and other types and activities for the promotion of accreditation and quality infrastructure.

The manner of organization and implementation of the activities will depend on the measures for dealing with the Covid-19 pandemic.

Required funds..... 1,500,000.00 MKD

8. Work of the IARNM Council and the Supervision Board of the Material-Financial Operation of IARNM

The IARNM Council consists of 11 members, and the Supervision Board of the Material-Financial Operation of IARNM consists of 3 members.

Required funds..... 1,935,000.00 MKD

9. International activities

IARNM is a full member of the European Accreditation Organization (EA), the International (World) Laboratory Accreditation Organization (ILAC), and the International Accreditation Forum (IAF).

As a full member of the three organizations, IARNM must participate in the annual meetings of the General Assemblies of EA, ILAC, and IAF, as it is a member with an active right and duty to participate and vote for new measures and resolutions in the field of accreditation worldwide, which should then be vertically transposed to the national level in an appropriate legal form. Also, IARNM employees must participate in the meetings within the Technical Committees of EA, ILAC, and IAF and their working groups, in order to contribute to the adoption of the documents of these organizations which have mandatory and advisory nature.

As a full member of the EA, part of the staff is planned to be included as evaluators within the EA teams for evaluation and re-evaluation of other accreditation bodies - signatories to the EA MLA Agreement. The Institute is obliged to deliver this activity for EA in a certain number of evaluation days, for which already trained assessors-employees in IARNM will be hired, and training of other assessors is underway. Participation in EA assessment missions is at the expense of the national accreditation body from which assessment team members are delegated.

On the basis of full membership, IARNM is obliged to pay an appropriate amount in the name of an annual membership fee for 2022, namely:

- on the basis of full membership in EA and the signatory status to the MLA Agreement, IARNM should pay an annual membership fee in the amount of EUR 10,737.00.

- on the basis of full membership in ILAC and the signatory status to the MRA Agreement, IARNM is obliged to pay an annual membership fee in the amount of 4.930,00 Australian dollars,

- on the basis of full membership in IAF and the signatory status to the MLA Agreement, IARNM is obliged to pay an annual membership fee in the amount of 1.695,00 US dollars.

IARNM will also maintain and upgrade its cooperation with the national accreditation bodies from the region in accordance with the signed bilateral agreements with Serbia, Montenegro, Bulgaria, Albania, Croatia, Turkey, Kosovo, Bosnia and Herzegovina, and Moldova. IARNM will actively contribute to the concluded Agreement for cooperation with the national accreditation bodies of the countries in the region within the initiative "Open Balkans".

IARNM will also maintain and upgrade cooperation agreements with the UK Accreditation Service (UKAS), the German Accreditation Body (DAkkS), and the Federal Accreditation Service of the Russian Federation (RusAccreditation).

IARNM shall proceed to conclude new cooperation agreements with other national accreditation bodies. As part of the established intergovernmental cooperation, IARNM has undertaken initial activities for concluding a bilateral cooperation agreement with the Ukrainian Accreditation Body.

The purpose of these agreements is the organization of joint training for assessors, exchange of experts and assessors at a regional level, and cross-border accreditation that will contribute to the construction of an efficient accreditation system. Within the agreed regional cooperation, the activities of mutual participation in monitoring during the performance of assessments by the national accreditation bodies from the region will continue.

Required funds..... 3,500,000.00 MKD

10. Management and current operation of IARNM

For the smooth execution of the current activities of IARNM, especially in conditions of a pandemic and organization of work and performance of assessments at a distance using appropriate ICT technology, IARNM's Budget for 2022 provides funds for maintenance and upgrading of ICT - infrastructure, digitalization of the overall operation of IARNM through maintenance and upgrading of the unique accreditation information system (AIS) within the ERP* system of IARNM, replacement of technologically obsolete equipment, maintenance and upgrading of hardware and software solutions, which should provide effective, efficient, safe and secure operation of the Institute. *The ERP system covers software solutions for the AIS-Data management system for accreditation procedures including registers for accredited bodies, assessors, and experts, software solutions for accounting, payroll, cash register, electronic archiving, and human resources. The digitalization process is also in line with the government project for digitalization and providing easy access to services for end-users. The current maintenance includes maintenance and upgrade of the software for accounting, treasury, and archival operations, maintenance of the premises, maintenance of vehicles, procurement of information and communication equipment, etc.

Required funds 3,300,000.00 MKD

IV. Final provisions

1. Up to 31.03.2023 IARNM shall submit a Report with financial indicators for the implementation of IARNM's Work Programme for 2022 to the Government of the Republic of North Macedonia, which will include the achieved results and financial indicators, as well as an explanation for possible deviations from the projected activities.

2. This Programme shall enter into force on the day following the day of its publication in the "Official Gazette of the Republic of North Macedonia".

No. _____

_____2022
Skopje

**President of the
Government of the Republic of North Macedonia,
Dimitar Kovachevski**