



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

PROPOSAL

**WORKING PROGRAM
of the Institute for Accreditation
of the Republic of North Macedonia
for the year 2025**

Act: PR 2025

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 _____2025, adopted the following

Working Program of the Institute for Accreditation of the Republic of North Macedonia for the year 2025

I. Introduction

According 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 accordance with the prescribed accreditation procedure based on this and other laws and supervises the fulfillment of accreditation requirements.

The accreditation is a procedure for formal recognition of the capacity to perform certain activities in the sense that a certain conformity assessment body fulfills the requirements stipulated by national, European and international standards, relevant legislation, IARNM procedures, as well as the recommendations of the European and global accreditation organizations. 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 the following:

- 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 which 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 global trade facilitation. 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. Considering the fact that IARNM is a signatory to three significant international agreements that provide this benefit, the same also applies to domestic products and services when they are placed 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 accreditation certificates, namely:

- with the European co-operation for Accreditation (EA), it is a signatory to EA-MLA (Multilateral Agreement – MLA¹),
- with the International (global) Organization for Accreditation of Laboratories, Inspection Bodies and Proficiency Testing Providers (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 the acceptance of certificates and reports issued by accredited conformity assessment bodies worldwide.

By signing these Agreements, IARNM opened the doors for domestic products and services to the European and global markets, in accordance with the principle "accredited once, accepted everywhere".

Namely, the main benefit of the Agreements is that the documents issued by 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, 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 the European and global level.

The successful implementation of the key commitments of IARNM on an 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 Working Program for the year 2025

Strategic interest and objective of IARNM is to continuously maintain and strengthen the accreditation system, which will provide confidence in the competence of conformity assessment bodies (certification bodies, testing and calibration laboratories, medical laboratories and inspection bodies) and the documents issued thereby, and at the same time ensure free trade in domestic products and services to the European and global markets.

Accreditation, both globally and in the Republic of North Macedonia, plays a pivotal role in strengthening the internal market, quality and safety 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 and as a support for its integration into the European Union.

Taking into consideration the benefits from the realization of the previously outlined plans and objectives of IARNM, that represent acknowledgment for the successful performance of the accreditation activity, as well as the potentials arising from them, their multipurpose significance should also be considered.

¹ EA-MLA is an agreement signed between 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, 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.

Hence, the main activities of IARNM in 2025 shall be directed towards maintaining and upgrading the quality management system in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018, as a basic condition for maintaining the agreements.

1. Primary objective for the implementation of the Program:

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

2. The specific objectives for the implementation of the Program are:

- implementation of annual activities related to assessment procedures for maintaining accreditation of already accredited bodies and implementation of procedures for initial assessment and progressive increase in the number of accredited bodies by IARNM, which will depend on institutional strengthening through new personnel and organizational solutions,
- 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 employees in IARNM,
- preparation for the upcoming fourth re-evaluation by EA after signing the EA-MLA Agreement,
- constant commitment to facilitating global trade through acceptance of the results of accredited conformity assessment bodies,
- increasing the activity of technical committees in order to provide necessary technical support for accreditation activities,
- promoting the benefits of the accredited activities of 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 on all issues related to accreditation procedures,
- active regional cooperation and cooperation with European and international accreditation organizations,
- ongoing activities to gain greater trust among stakeholders,
- strengthening the already established cooperation with the Chambers of Commerce in the Republic of North Macedonia, the Consumer's Organization of the Republic of North Macedonia, economic operators and other business entities,
- strengthening and expanding cooperation with national accreditation bodies from the region, Europe and the world, and
- participation in the implementation of international projects.

The realization of the program objectives will be ensured through the funds provided within the Budget of the Republic of North Macedonia for 2025, as well as through participation in projects such as: TAIEX - Instrument of the European Commission, GIZ - the German Society for International Cooperation and other project activities.

III. Projected activities for the implementation of the Program

In the Budget of the Republic of North Macedonia for 2025 ("Official Gazette of the Republic of North Macedonia" No. 254/24), section 10001 - Ministry of Economy, in the subprogram 51 - IARNM, for the categories 40 - Salaries and allowances, 42 - Goods and

services and 48 - Capital expenditures, financial resources are planned in the amount of 12,540,000.00 MKD on account 637/603, 32,776,000.00 MKD on account 631 or a total of 45,316,000.00 MKD.

- About 26% of the funds are intended for salaries of employees from the Budget of the Republic of North Macedonia - account 637/603 IARNM.
- About 66% are intended for goods and services from accounts 637/603 and 631 IARNM.
- About 8% of the funds are intended for capital expenditures.

Institute for Accreditation of the Republic of North Macedonia

Category Item	Description	Budget 2025 (in 000 MKD)		Total expenditures
		637/603	631	
	Expenditures	12,540	32,776	45,316
40	Salaries and allowances	11,850	0	11,850
401	Basic salaries	8,300		8,300
402	Social security contributions	3,300		3,300
404	Allowances	250		250
42	Goods and services	690	29250	29940
420	Travel and daily expenses	0	1,950	1,950
421	Utilities, heating, communication, transport	50	4,000	4,050
423	Materials and small inventory	40	1,500	1,540
424	Repairs and ongoing maintenance	100	3,300	3,400
425	Contracted services	500	13,500	14,000
426	Other current expenses		5,000	5,000
427	Temporary employment		0	0
46	Subsidies and transfers	0	200	200
464	Other transfers		200	200
48	Capital expenditures	0	3326	3326
480	Purchase of equipment and machinery		816	816
481	Construction sites		510	510
485	Investment and non-financial assets		2,000	2,000

To review and maintain the efficiency and upgrade the established national accreditation system in accordance with the Law on Accreditation, the standard MKC EN ISO/IEC 17011:2018, the rules of the European co-operation Accreditation, the International Laboratory Accreditation Cooperation and the International Accreditation Forum (EA, ILAC and IAF) and the internal documents of IARNM, the following activities need to be implemented:

1. Accreditation activities

In the official register of IARNM at the moment of preparation of this program, there are 222 active accredited conformity assessment bodies, and procedures are underway for new applications for accreditation. In 2025, regular inspections of already accredited bodies will be carried out, and IARNM will also act on newly submitted applications for accreditation, based on

which it expects an increase in the number of accredited conformity assessment bodies. In 2025, IARNM will focus on implementing the prepared plan for transition to the new standard MKC EN ISO 15189:2022, and it is expected that the accredited medical laboratories that have submitted an application for accreditation to the new standard will complete the transition.

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, due to a lack of professional and competent staff, IARNM is currently facing a problem in responding to a possible challenge to develop new schemes and areas for accreditation. Otherwise, these activities are carried out in the event of a submitted request and market research which should be carried out in cooperation with the stakeholders, assisted by the work of the Technical Committees, in accordance with the specific needs of the Republic of North Macedonia and the needs of the clients.

The eventual development of the new schemes and areas is a precondition for the institutional strengthening and improvement of the capacities of IARNM, which also implies an increase in the salaries of the employees, which are the lowest compared to similar regional institutions, which is a basic precondition to prevent staff attrition and ensure impartiality and independence in work.

Also, during 2025, the activities for performing accreditation activities abroad will continue, in accordance with the rules for cross-border accreditation.

Required funds 20,981,000.00 MKD

2. Preparation for the fourth regular re-evaluation after signing the Multilateral Agreement with the European co-operation for Accreditation (EA-MLA)

According to the rules, plans and working program of the European co-operation for Accreditation (EA), the fourth regular supervision after signing of the Multilateral Agreement with the European co-operation for Accreditation (EA-MLA) should be implemented in 2026. The supervisory assessment will include an overall assessment of the accreditation system and the operation of IARNM, hence in the current year the focus of interest will be on undertaking preparatory activities for internal reassessment and improvement of the system and overall operation before the assessment. The activities will include upgrading and revising the documents of the IARNM quality system, staff strengthening, upgrading of competencies through educational activities, activities for work harmonization, planning of organizational and technical resources and sources for organizing the assessment, and more.

3. Training organization

Maintaining and upgrading the competence of both the employed assessors and the external assessors and experts of IARNM is essential, but also a primary obligation that arises for IARNM from the international agreements, as it is a basic precondition for high-quality and proper performance of accreditation procedures.

At the time of preparation of this program, the List of Active Assessors and Experts consists of 35 leading assessors, 116 technical assessors and 76 experts. Eight of the leading assessors are from the employees of IARNM, and the rest are external collaborators. In addition to assessors and experts from the Republic of North Macedonia, the list include assessors and experts from

other accreditation bodies, which 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 expressed needs for accreditation, technical assessors and experts from abroad are also engaged in the accreditation procedures. The percentage of their engagement is decreasing from year to year, because 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 2025, attention will be paid to strengthening the pool of assessors by ensuring participation in trainings, seminars and workshops with the participation of candidates for assessors and technical assessors, and training with involvement in supervised assessments.

In 2025, IARNM plans to organize or provide participation in the following trainings/workshops:

- Training for the employees and members of the IARNM Council for the requirements of the standard MKC EN ISO/IEC 17011:2018 - General requirements for accreditation bodies accrediting conformity assessment bodies, the standard according to which IARNM operates and on the internal rules and procedures (mandatory, for the purpose of maintaining the accreditation system),
- Training for harmonization of assessors and coordinators in IARNM,
- 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,
- Workshops within the Technical Committees related to the accreditation criteria given in the IARNM Rulebooks (if necessary),
- Training for assessors for ISO/IEC 17024 for certification bodies for personnel,
- Training for the requirements of ISO 22000 and ISO 22003,
- Training for the requirements of ISO/IEC 27001 and ISO/IEC 27006,
- Training in clinical and forensic autopsy (if a suitable training provider is available),
- Training for forensic modules according to ISO 17025 and ILAC G19,
- Training for ISO 20387 (Biobanking),
- Exchange of experiences related to risks to impartiality and the accreditation process,
- Training for the requirements of the standard EN ISO/IEC 17011:2017 - (exchange of experiences),
- Training for trainers on the requirements of the standard ISO/IEC 17043:2023 - general requirements for the competence of proficiency testing providers,
- Training/workshop on the requirements for the new edition of the standard ISO 15189:2022 for medical laboratories intended for lead and technical assessors for medical laboratories,
- Trainings on the quality of agricultural products (PDO, PGI and TSI),
- Training for flexible scope accreditation,
- Training for the requirements of the standard EN ISO/IEC 17025:2017,
- Training on specific requirements of the standard EN ISO/IEC 17025:2017 - measurement uncertainty and rules for declaration of conformity,
- Accreditation training for notification/approval/authorization purposes in the area of Regulation (EU) 305/2011 (CPR – Construction Products),
- Training on the new Construction Products Regulation (EC) 2024/3110 and the use of the CE marking on construction products,

- Accreditation training for notification/authorization in relation to Directive 2010/35/EU (TPED-Transportable Pressure Equipment) in addition to ADR/ADN/RID,
- Training for validation and verification, EN ISO/IEC 17029 and EN ISO 14065,
- Training for EA assessors,
- Trainings/workshops organized by the EA Committees,
- Training on changes to the standard 17020:2012,
- Training for documents from European and international accreditation organizations (if deemed necessary),
- Training for assessors in the field of organic production (with all its specifics), especially organic production in third countries and for Regulation 848/2018,
- Training on ISO 16140-1:2016 Microbiology of the Food Chain.

The trainings will be organized according to the planned project activities and the training plan, the expressed needs, and will be attended by employees of IARNM and stakeholders, assessors and experts.

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

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

Required funds 2,000,000.00 MKD

4. Human resources

A total of 13 administrative staff are regularly employed at the Institute for Accreditation of the Republic of North Macedonia.

In recent years, the Institute has continuously recorded an outflow of staff on various grounds and it is essential, but also an obligation, in accordance with the requirements of the standard 17011:2018 and the rules of the European and international accreditation organizations, to ensure, or rather to have, an adequate staff capacity of professional and competent persons. Hence, in the current year, it is mandatory to realize employment of a larger number of executors and promotions and salary increases, in order to ensure optimal human resources as a basic requirement of the rules for the organizational and functional setup of a national accreditation body. The work funds have provided finances for salaries, as well as for other allowances for other employment rights.

Required funds11,850,000.00 MKD

5. Digitalization of the work process of IARNM

IARNM is implementing digital transformation process of workflows. A unique accreditation information system (AIS) has been introduced as an integrated software solution, and the services for its maintenance and upgrading are provided by concluding public procurement contracts. Currently, work is being performed simultaneously on paper and in electronic form, and in 2025 it is planned to test several different portals to support digital operations, after which they would be put into operation. Cyber security of the workflow is also ensured through the procurement and use of licensed software programs and antivirus protection,

as well as through the procurement of a system upgrade to provide Disaster recovery (DR) protection.

Required funds 2,000,000.00 MKD

6. Cooperation with state authorities

IARNM will continue with activities to deepen active cooperation with the state authorities through participation in the work of several working groups formed by the Government of the Republic of North Macedonia, the Ministry of Economy and Labor, the Ministry of Environment and Spatial Planning and the Ministry of Agriculture, Forestry and Water Management, the Bureau of Metrology, the Ministry of Digital Transformation, the Ministry of Finance-Public Procurement Bureau, as well as other line ministries and state authorities.

Also, IARNM will continue to participate in the work of the Technical Committees in the Institute for Standardization of the Republic of North Macedonia.

Cooperation can also be established with other entities that can contribute in partnership and strategically to the promotion of accreditation and its importance and improving the state of the quality infrastructure by bringing together all stakeholders of the national quality infrastructure and interested parties in an appropriate legal entity at the level of the Macedonian Quality Society (universities, state authorities, consumer organizations, chambers of commerce, representatives of the business community).

Required funds 150,000.00 MKD

7. Conducting internal inspections

According to the requirements of the standard MKC EN ISO/IEC 17011:2018, the implementation of the regular internal inspection of the employees in IARNM is a mandatory obligation and a necessity for the maintenance and improvement of the quality management system in IARNM. The internal inspection in 2025 will be conducted in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018.

8. Management re-evaluation

In accordance with the Quality Policy and Operating 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 sectors and departments) is carried out once a year.

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

9. Promotion of the accreditation system

The promotion of the accreditation system is crucial for raising awareness of the importance and role of accreditation in everyday life and the economy. It is necessary to inform the public about the application procedure and the procedure for obtaining the status of an accredited body, i.e., to bring stakeholders closer to the requirements for accreditation, as well as to promote its benefits.

Independently or in cooperation with relevant stakeholders in the economy, IARNM plans to organize promotional events by which all stakeholders will be informed about the benefits and usefulness of signing the international agreements EA-MLA, ILAC-MRA, IAF-MLA and the use of the signs proving their signatory 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 the European and global accreditation organizations,
- Media promotion of accreditation,
- Issuance of the Annual Report on the work of IARNM for 2024,
- Promotion for awarding certificates to accredited bodies, on the occasion of June 9th, the "World Accreditation Day",
- Organizing and/or participating in conferences or other types of gatherings on topics relevant to the role of accreditation,
- Maintenance and upgrade of the official website of IARNM.

Required funds1,700,000.00 MKD

10. Work of the IARNM Council and the Supervision Board for Material and Financial Operation of IARNM

According to the Law on Accreditation, the IARNM Council consists of 11 members, and the Supervision Board for Material and Financial Operation of IARNM consists of 3 members.

At the time of preparation of the Program, the Council has and operates with a total of 8 appointed members and needs to be completed with 3 more members.

Required funds 1,935,000.00 MKD

11. International activities

IARNM is a full member of the European co-operation for Accreditation (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 on 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 of 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 are of a mandatory and advisory nature.

As a full member of EA, part of the staff are included as evaluators within the EA teams for evaluation and re-evaluation of other accreditation bodies that are signatories to the EA MLA Agreement. The Institute is obliged to deliver this activity to EA in a certain number of evaluation days, and training of other evaluators is also in the process. Participation in EA

evaluation missions is at the expense of the national accreditation body from which the members of the evaluation team are delegated.

Based on full membership, IARNM is obliged to pay an appropriate amount as annual membership fee for 2025, as follows:

- Based on full membership in EA and status as a signatory to the MLA Agreement, IARNM is obliged to pay an annual membership fee in the amount of 10,800.00 EUR.
- Based on full membership in ILAC and status as a signatory to the MRA Agreement, IARNM is obliged to pay an annual membership fee in the amount of 5,100.00 AUD,
- Based on full membership in the IAF and status as a signatory to the MLA Agreement, IARNM is obligated to pay an annual membership fee in the amount of 1,700.00 USD.

IARNM will maintain and upgrade the 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 also actively contributes 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 the cooperation agreements concluded with the United Kingdom Accreditation Service (UKAS), the German Accreditation Body (DAkkS), the Federal Accreditation Service of the Russian Federation (RusAccreditation), as well as the Agreement with the Bulgarian Accreditation (BAS), the Czech Accreditation (CAI) and the Slovenian Accreditation (SA).

According to the expressed needs, IARNM will proceed to conclude new cooperation agreements with other national accreditation bodies.

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

Required funds 3,000,000.00 MKD

12. Management and current operation of IARNM

For the smooth execution of the current activities of IARNM, funds for the operation of IARNM are provided in the IARNM's Budget for 2025, whereby the same have been meticulously planned for maintenance and upgrade of the ICT infrastructure, digitalization of the overall operation of IARNM through the maintenance and upgrade of the unique accreditation information system (AIS), replacement of technologically outdated equipment, maintenance and upgrade of hardware and software solutions, which should provide effective, efficient, reliable and safe operation of the Institute. 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 also includes maintenance of premises, maintenance of means of transportation, procurement of information and communication equipment, etc.

Required funds 1,700,000.00 MKD

IV. Final provisions

By 31.03.2026, IARNM shall submit a Report on the Implementation of the Working Program of the IARNM for the year 2025 to the Government of the Republic of North

Macedonia, which will include the achieved results and financial indicators, as well as an explanation of any deviations from the planned activities.

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

No. _____
_____ 2025
Skopje

**President of the
Government of the Republic of North Macedonia,
Prof. Dr. Hristijan Mickoski**