



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

**WORK PROGRAMME
of the Institute for Accreditation of the
Republic of North Macedonia
for year 2021**

Act: PR 2021

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 _____ 2021 adopted the following

Work Programme of the Institute for Accreditation of the Republic of North Macedonia for year 2021

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 fulfils 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 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. Taken 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 to 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

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, ILAC members, for the recognition of equality and confidentiality, and thus the acceptance of accredited inspection certificates and test reports worldwide.

- 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 the 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 international level so far is only an additional incentive, but also an obligation to fulfil the strategic interest and vision of IARNM in order to maintain and strengthen the status of a full member in international accreditation organizations.

The realization of activities contained in this Programme will also represent the basis and preparation of IARNM for the next regular peer-evaluation assessment by EA, which is already planned for realization at the end of November and the first week of December 2021.

II. Objectives of the IARNM Work Programme for year 2021

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, 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.

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 multi-purpose significance should also be considered.

Hence, the main activities of IARNM in 2021 aim at 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.

- Primary objective for Programme realisation:

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 works and conducts the accreditation procedures.

The self-assessment report of IARNM EA 2/02 T01 was positively evaluated by the EA in terms of the manner of implementation of the new standard requirements and the degree of

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.

satisfaction, based on which it was concluded that IARNM performed successful transition to the requirements of the standard.

- Specific objectives for Programme realisation 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,
 - 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,
 - strengthening 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 2021, as well as through participation in projects such as: TAIEX – an Instrument of the European Commission, PTB and others.

III. Projected activities for Programme realisation

The Budget of the Republic of North Macedonia for 2021, 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 8,850,000.00 on account 637/603, and MKD 34,300,000.00 on account 631, or a total of MKD 43,150,000.00.

- 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 65% are intended for goods and services from account 637/603 and 631 IARNM.
- About 2% of the approved funds are intended for subsidies and transfers (for retirement severance pay).
- About 13% of the funds are intended for capital expenditures.

Institute for Accreditation of the Republic of North Macedonia

Category Item	Description	Budget 2021 (in 000 MKD)		Total expenditures
		637/603	631	
	Expenditures	8,850	34,300	43,150
40	Salaries and allowances	8,500		8,500
401	Basic salaries	6,100		6,100

402	Social security contributions	2,400		2,400
42	Goods and services	350	27,600	27,950
420	Travel and daily expenses	50	2,800	2,850
421	Utilities, heating, communication, transport	50	2,000	2,050
423	Materials and small inventory	50	1,000	1,050
424	Repairs and ongoing maintenance	100	2,500	2,600
425	Contracted services	100	14,000	14,100
426	Other current expenses		3,800	3,800
427	Temporary employment		1,500	1,500
46	Subsidies and transfers		1,000	1,000
464	Various transfers		1,000	1,000
48	Capital expenditures		5,700	5,700
480	Purchase of equipment and machinery		1,500	1,500
481	Construction buildings		300	300
485	Investment and non-financial assets		2,100	2,100
486	Purchase of vehicle		1,800	1,800

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 192 active accredited bodies for conformity assessment, and procedures are underway for new accreditation applications. In 2021, 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.

Also, the activities for performing accreditation activities abroad will continue in the course of 2021, in line with the rules for cross-border accreditation.

Required funds 21,165,000.00 MKD

2. Third regular re-evaluation following the signing of the Agreement on mutual recognition of accreditation certificates with the European Accreditation Organization (EA-MLA)

Pursuant to the rules, plans and work programme of the European Accreditation Organization (EA), the third regular re-evaluation (supervision) following the signing of the Agreement on mutual recognition of accreditation certificates with the European Accreditation Organization (EA-MLA) should be realized in the period November 29 - December 3, 2021. The assessment will include an overall assessment of the accreditation system by means of evaluating the overall material and human resources available to the Institute, due to which the Institute has an obligation to engage and strengthen human resources through promotions and employment of new executors and strengthen the pool of assessors and experts in the forthcoming period. The assessment will be conducted by a multi-member international team delegated by EA. The overall organization and costs for the realization of the activity shall be borne by IARNM (travel costs, food and accommodation costs).

Maintaining the importance of the Agreement through the presentation and defence of the established accreditation system and fulfilment of the obligations arising from it through various activities are essential for the activity of IARNM, for the Macedonian economy and for the state.

3. Organising training

Maintaining and upgrading the competence of both employed assessors and external persons - assessors and experts of IARNM is an essential need, but also a primary obligation arising for IARNM from international agreements, as it is a basic prerequisite 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 24 Lead Assessors, 68 Technical Assessors, 6 Assessors in Training and 47 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 2021, account will be taken to strengthen the pool of assessors by ensuring the participation in trainings, seminars and workshops with the participation of candidates for assessors and technical assessors and training with involvement in supervised assessments.

In the course of 2021, IARNM plans to organize or ensure participation in the following trainings/workshops:

- Trainings 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 new and revised requirements of the European Regulation 848/2018 (Organic production),
- Workshop on certification bodies for products with protected designation of origin, protected geographical designation and a designation of guaranteed traditional specialty,

- Training for accreditation of certification bodies for certification of management systems, certification according to ISO/IEC 20000-1:2018 for Information Technology - Service Management - Part 1: Requirements for service management,
- 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),
- 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, and
- 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.

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

Also, the Annual Training Plan for the IARNM employees will involve generic and specialized trainings 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 14 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 employments 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 employment rights, such as the right to recourse for annual leave for 2021 in accordance with the Civil Collective Agreement for state administration bodies, professional services of the Government of the Republic of North Macedonia, courts, public prosecutor's offices, penitentiary and correctional institutions, state ombudsman, municipalities, the City of Skopje and the municipalities of the City of Skopje, agencies, funds and other bodies established by the Assembly of the Republic of North Macedonia ("Official Gazette of the Republic of North Macedonia" no. 51/20).

Required funds..... 9,800,000.00 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 and the Ministry of Agriculture, Forestry and Water Economy, as well as other competent ministries.

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 to 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 inspection

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 2021 will be conducted in accordance with the requirements of the standard MKC EN ISO/IEC 17011:2018 and this is a key activity that will be evaluated by the EA in the framework of the upcoming monitoring assessment.

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 2021,
- 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; and
- 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 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

8. 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 are of 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 annual membership fee for 2021, 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 11,125.00,

- 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 5,082.00 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 1,745.00 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 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).

The purpose of these agreements is the organization of joint trainings for assessors, exchange of experts and assessors at regional level, 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 funds2,600,000.00 MKD

9. Management and current operation of the 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 2021 provides funds for maintenance and upgrading of ICT - infrastructure, replacement of outdated equipment, maintenance and upgrading of hardware and software solutions, which should ensure effective, efficient, safe and secure operation of the Institute. We place digitalization in the foreground of the process of processing applications for accreditation and implementation of accreditation procedures by upgrading and adapting the software for conducting accreditation procedures (Data management system). 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 3,500,000.00 MKD

IV. Final provisions

1. As of March 31, 2022, IARNM will submit a Report with financial indicators for the implementation of IARNM's Work Programme for 2021 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. _____

_____2021
Skopje

**President of the
Government of the Republic of North Macedonia,
Zoran Zaev**