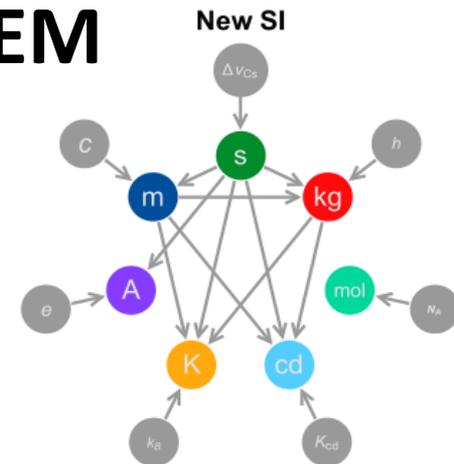
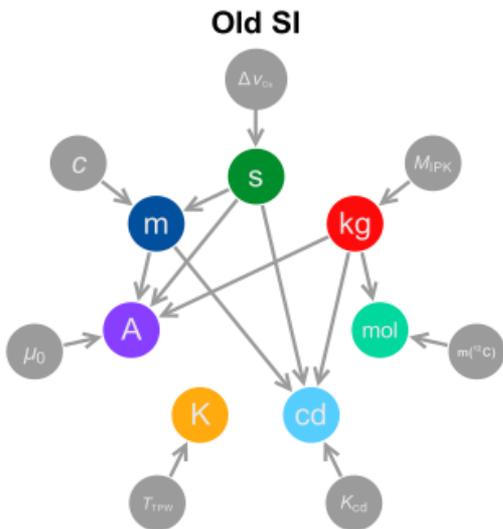




2ND RE-EVALUATION OF THE QUALITY MANAGEMENT SYSTEM



Bianka Mangutova-Stoilkovska, PhD



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

CONTENT

- Short History of Bureau of metrology (BoM)
- Quality infrastructure in Republic of North Macedonia
- General information about BoM
- Organizational structure of BoM
- Quality management system of BoM
- BoM in CIPM MRA and accreditation activities
- Improvement of BoM
- Feedback from the customers
- Implemented improvements
- Weak and Strong points
- Next steps for improvement



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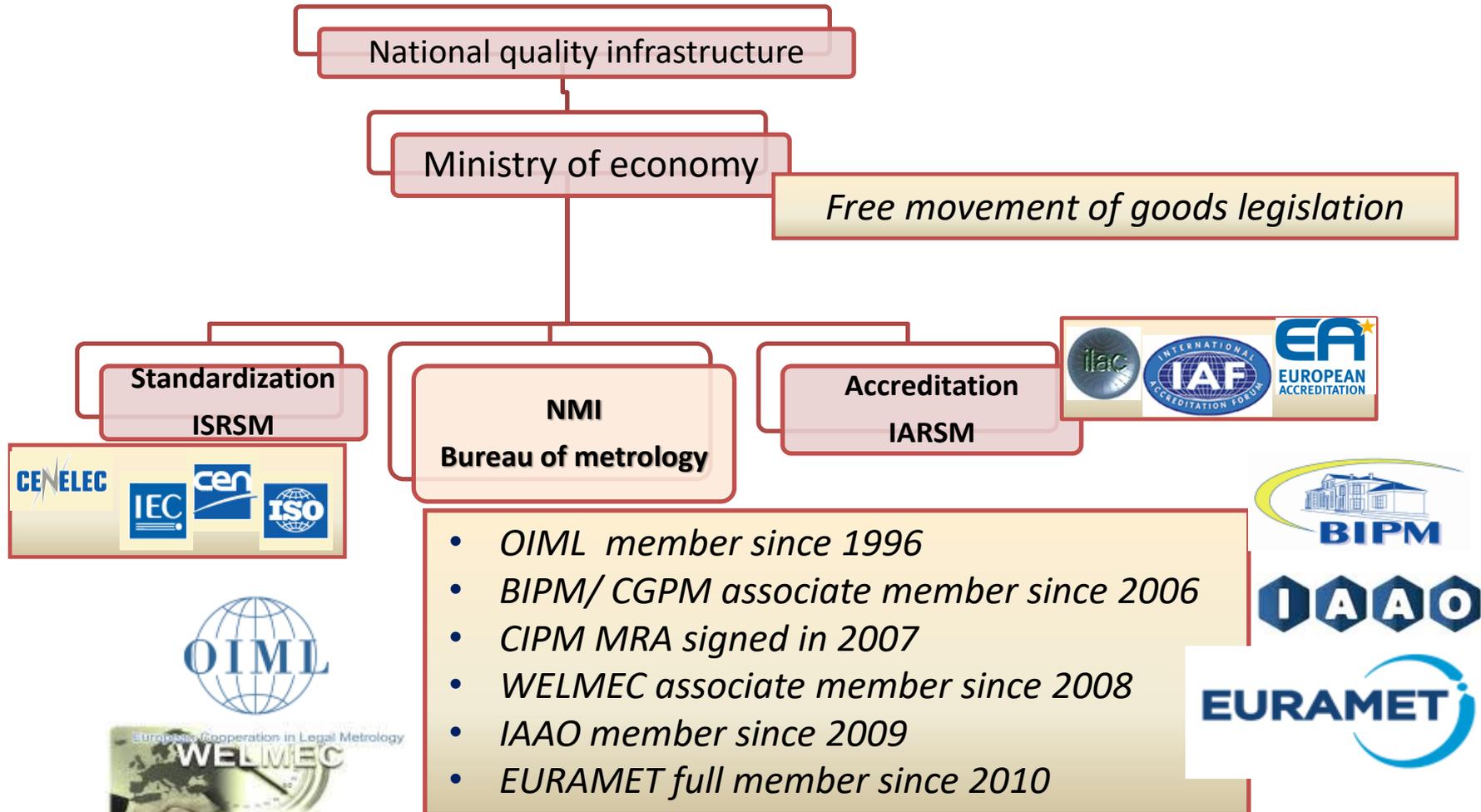
Short History

- May 1992 was founded Department for measuring instruments and precious metals within Ministry of Economy;
- April 1995 former Department has been transformed into Bureau for standardization and metrology, according to the new Macedonian Law on measuring unites and measuring instruments ("Official Gazette of RM" No.23/95);
- September 2001 Bureau for standardization and metrology has been transformed into Service for Standardization and Metrology, according to the Law on Government Bodies;
- July 2002 was founded Bureau of Metrology, according to the new harmonized Law on Metrology ("Official Gazette of RM" No.55/2002).



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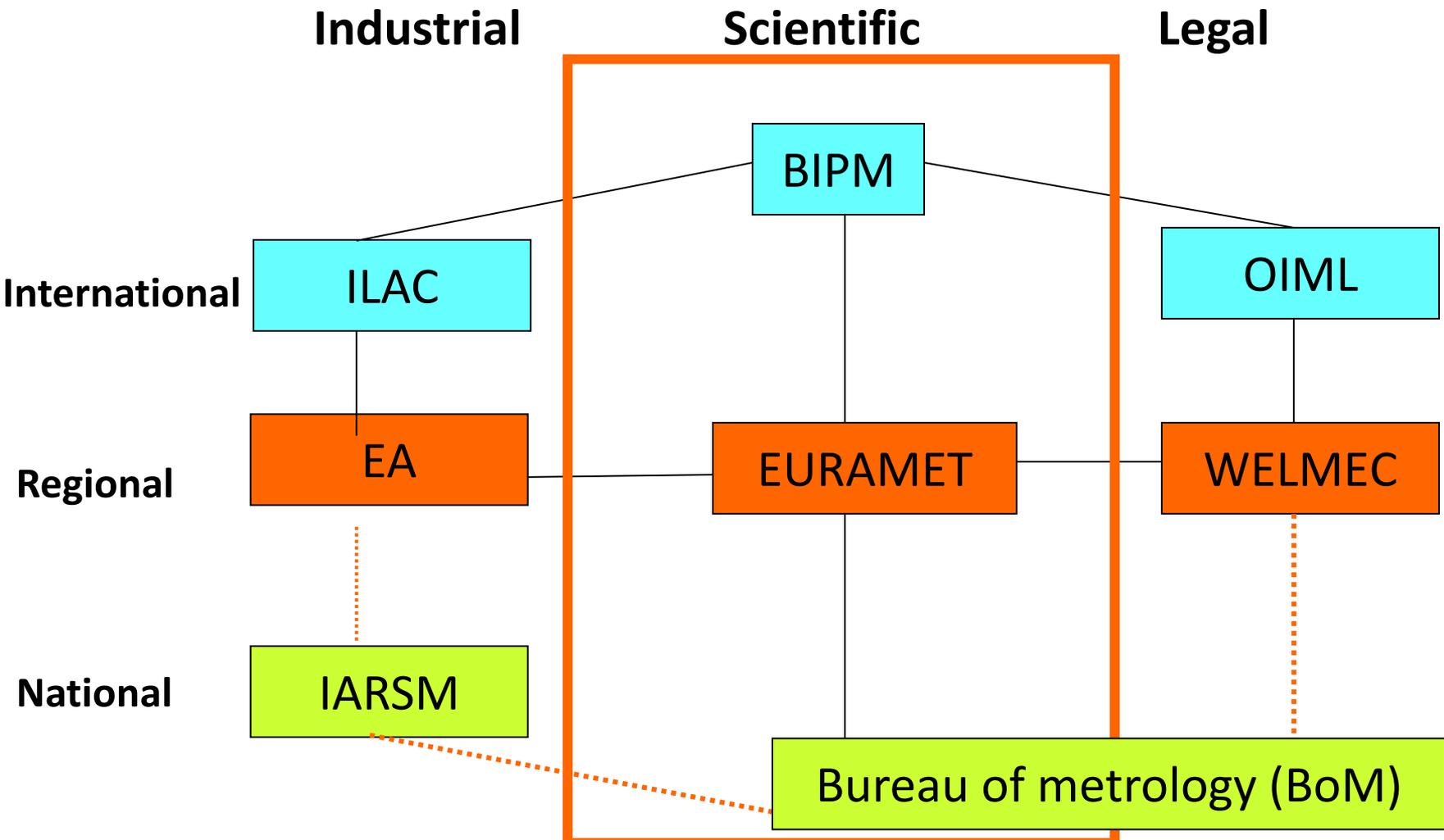
Quality infrastructure in Republic of North Macedonia





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Metrology - main part of Quality infrastructure





ID of Bureau of metrology (BoM)

- ✓ BoM is responsible governmental body for implementation of
 - **Law of metrology** (“Official Gazette of the Republic of Macedonia” No.55/2002)
 - **Law on control the goods of precious metals** (“Official Gazette of the Republic of Macedonia” No.23/92)
 - **Law of vehicles** (“Official Gazette of the Republic of Macedonia” No.140/08) – **administrative body**

- ✓ BoM fulfills the function of National Metrology Institute –NMI



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

Bureau of Metrology - National Metrology Institute

- Realization and maintenance of measuring standards
- International recognition of the national metrology infrastructure
- Ensuring traceability of measurements on International level
- Calibration of standards and measuring instruments



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

Bureau of Metrology in function of industrial/scientific metrology

Purpose

- Providing a framework for traceable and internationally recognized measurements
- Development of measurement procedures and methods
- Research
- Quality assurance
- Accredited activities



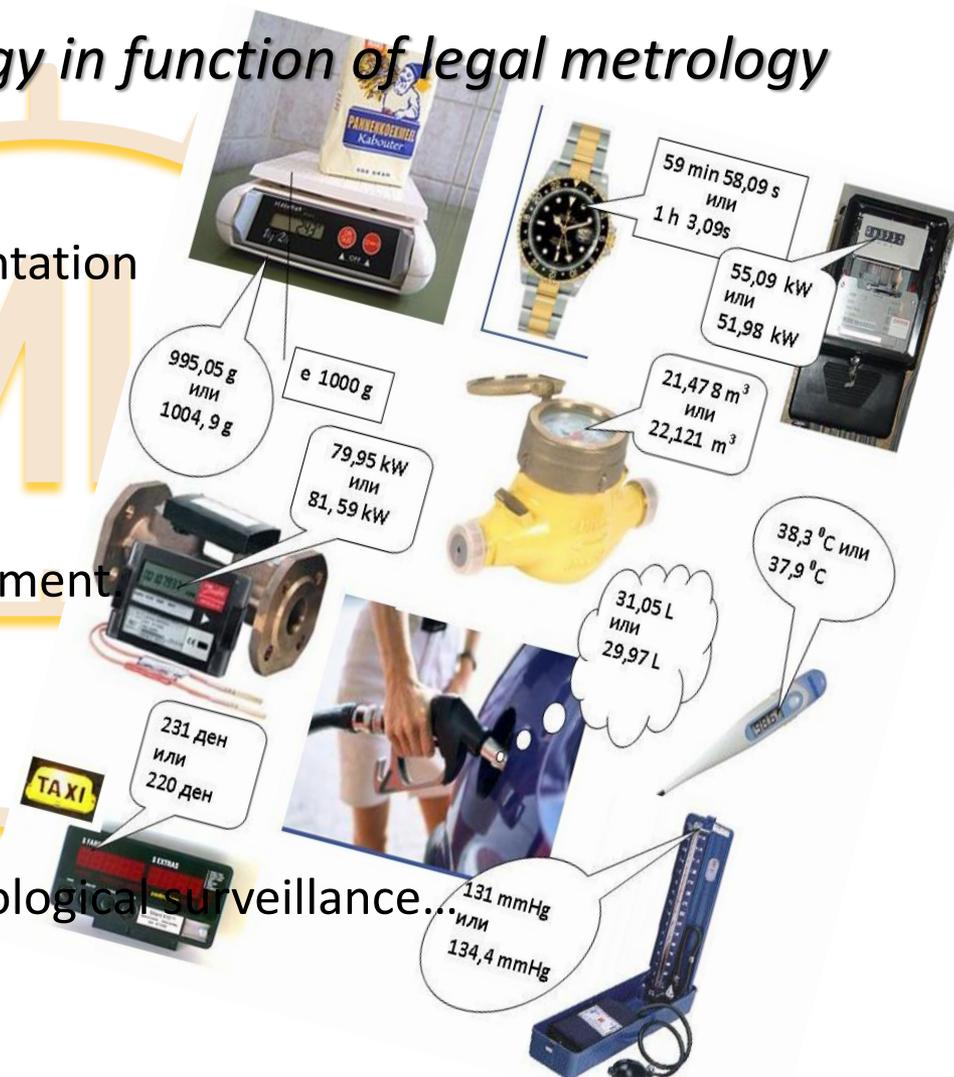


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Bureau of Metrology in function of legal metrology

Legal metrology - a branch of metrology that involves the implementation of regulations in order provide an appropriate level of quality and credibility for the results of measurements related to official controls, trade, health, safety environment

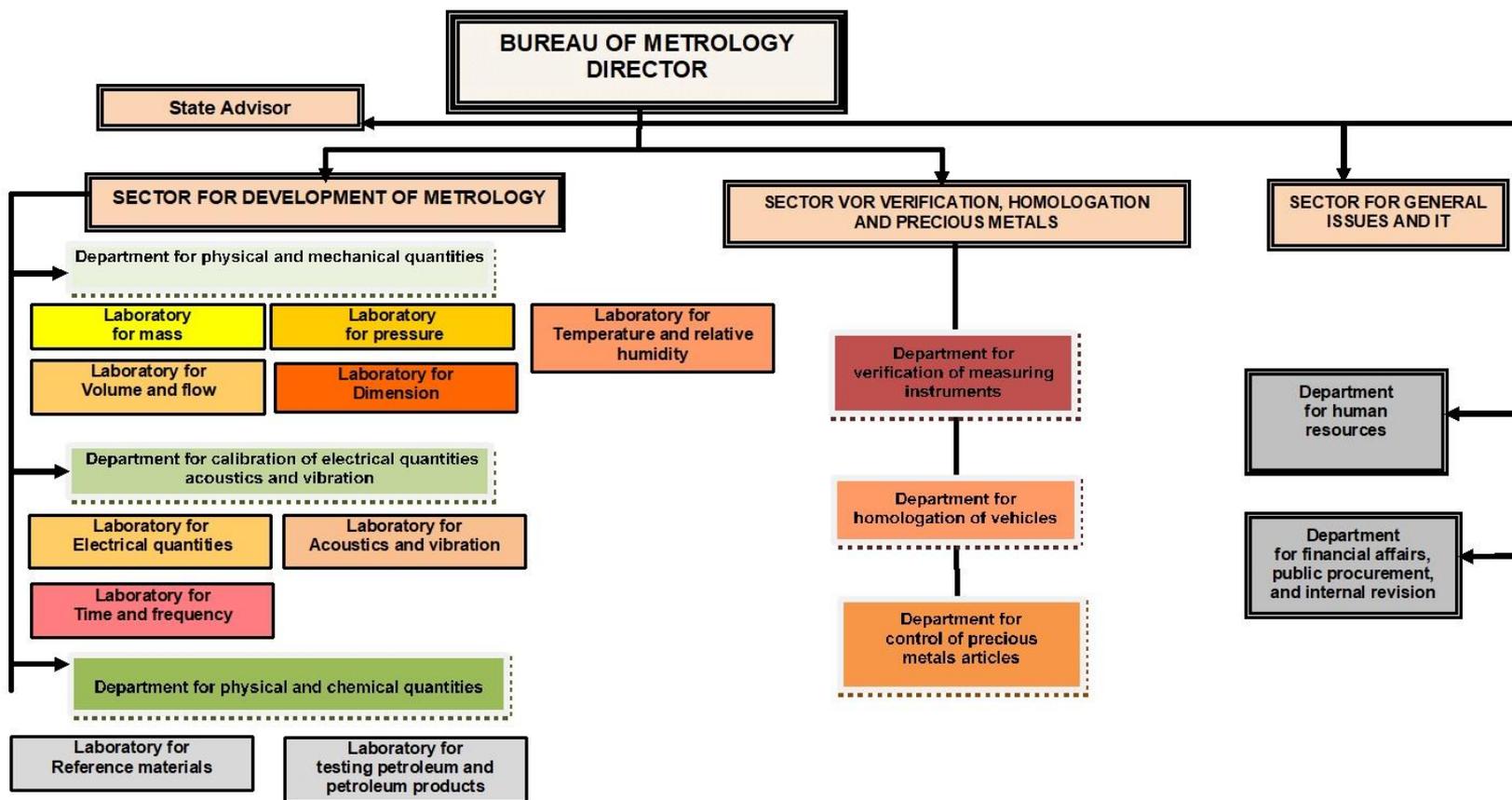
✓ BoM is responsible for performing initial and periodical verification of measuring instruments, control of pre-packed products, metrological surveillance.





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ORGANIZATIONAL STRUCTURE OF BoM

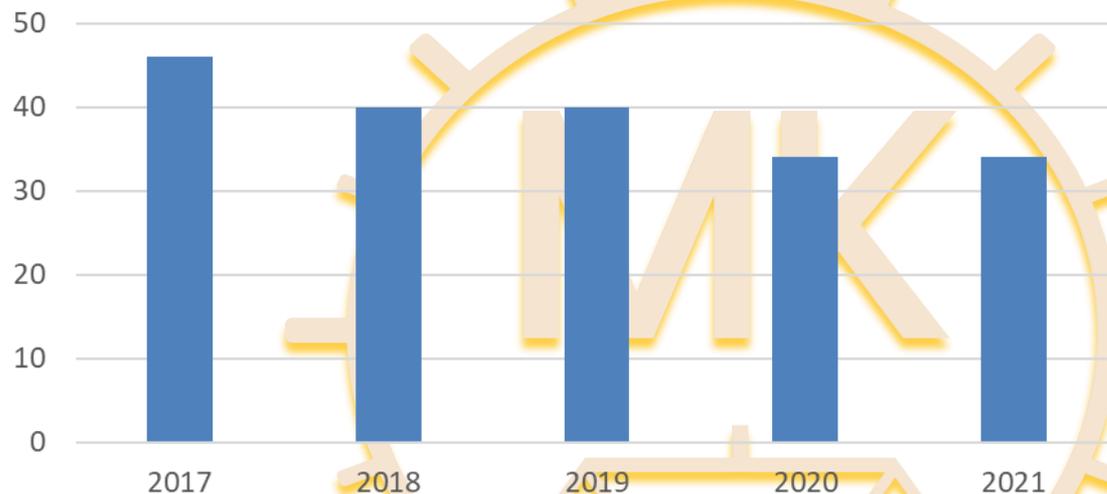




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ORGANIZATIONAL STRUCTURE OF BoM

Number of employees



- ✓ BoM currently has a total of 39 employees, 1/3 of them are in the Sector for development of metrology;
- ✓ During the years, BoM faced with decreasing number of overall employees, due to retirement or job change;
- ✓ Although the number of employees is decreasing slightly, BoM manage to respond to all requests of all interested parties.



KEY STAFF AND RESPONSIBILITIES in acc. to EN ISO/IEC 17025:2017

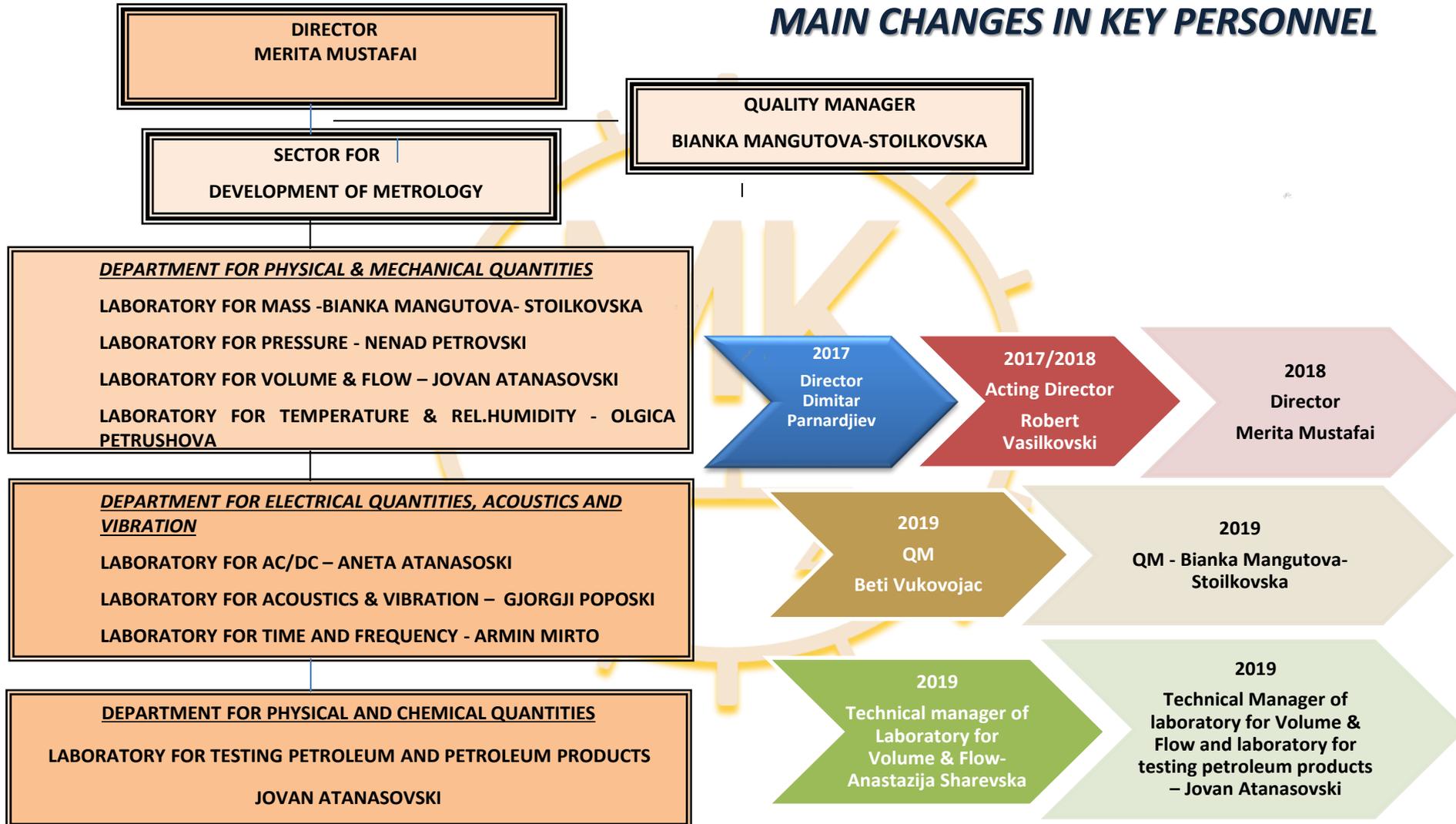
Key staff of BoM:

- Director
 - Quality Manager
 - Technical managers of the laboratories
- Organization, governance and coordination of the overall activities of the Bureau of Metrology;
 - Preparation of strategic documents for continuous development of BoM and national metrology infrastructure;
 - Implementation, maintaining and improvement of the Quality Management System/Determining the Quality Policy and its aims;
 - Approval of the QMS documents;
 - Ensuring that all necessary equipment and sufficient qualified personnel are available in the laboratories;
 - Recognition the fluctuation of staff as significant risk and defines actions in aim to reduce it;
 - Ensuring good communication within the organization.



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

MAIN CHANGES IN KEY PERSONNEL





QUALITY MANAGEMENT SYSTEM OF BoM

Mission and vision

- Construction of a sustainable and functional metrological system
- Providing a basis for stable measurements
- Measurements that are comparable
- Measurements that are coherent
- Measurements recognized outside the national framework
- Measurements that meet the needs of the economy, society and citizens



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Confidence in measurements



North Macedonia

Signatory/NMI

Bureau of Metrology, Ministry of Economy

→ BOM

Skopje

Participating in the CIPM MRA since: 14 November 2007
Signed by: Sonja MIRAKOVSKA (then Director, BOM)



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Mass
Length
Pressure
Volume & Flow
Electricity
Temperature
Time

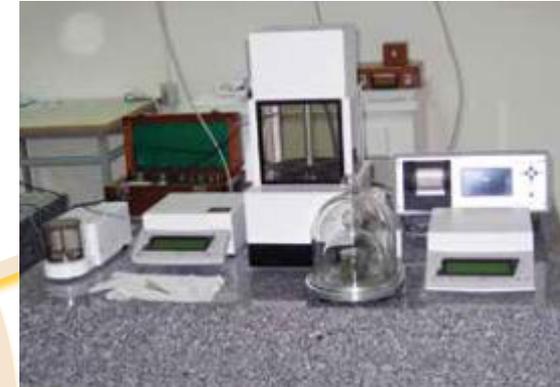




Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 Mass calibration laboratory

- Accredited on National level, since 2012 (weights and balances)
- 2013 - Published CMC in KCDB BIPM from 1 mg - 20 kg, E2 class
- IPA 2019 - Robotic mass comparator, with the range from 1 mg to 1 kg
- 2020 - Participation in EMPIR Real mass





Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 Laboratory for volume and flow

- Accredited on National level, since 2012
- 2013 - Published CMC in KCDB BIPM

Volume –

Gravimetric method - from 10 μL to 10000 ml

Volumetric method- from 2 L to 10000 L

Flow – from 0.02 to 90 m^3/h

- 2019 – Fluid flow, volume of liquid – merged and extended CMCs

Volume –

Gravimetric method - from 10 μL to 50 L

Volumetric method- from 2 L to 10000 L





Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 Pressure laboratory

- Accredited on National level, since 2012
- Preparation of CMCs for submission
- 2021 - Participation in EMPIR CEFTON





Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 Laboratory for temperature and relative humidity

- Accredited on National level, since 2012
- 2016 - Published CMCs for temperature in KCDB BIPM
- 2016-2018 Participation in EMPIR HUMEA
- 2020 - Preparation of CMCs for relative humidity
- 2021 - Regional Consultancy Fund for Quality Infrastructure (SEE QI-Fund) - Infrared calibrator for calibration/testing of infrared thermometers





Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 – Accreditation of laboratories for electrical quantities, acoustic, time and frequency

2016 - 2021

- ✓ Laboratory for AC/DC LF
- ✓ Laboratory for acoustic and vibration

2017 - In February, Time and frequency lab officially starts sending data to BIPM - data published Circular T publication

2021 Accreditation of the laboratory

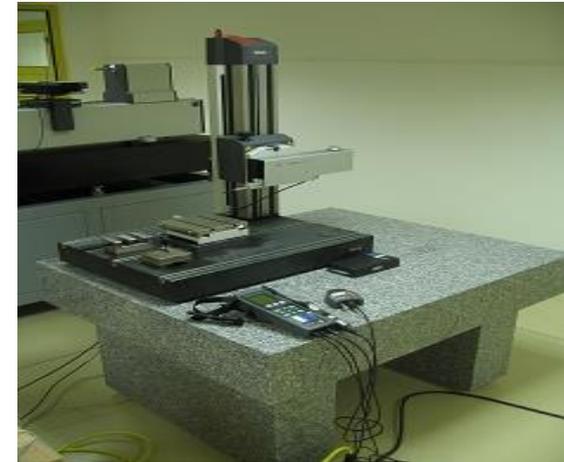




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IMPROVEMENTS 2017-2021

IPA 2019 - Laboratory for
length and angle



IPA 2019 - Laboratory for
reference materials
(production of ethanol in
water and testing of
breath analyzers).





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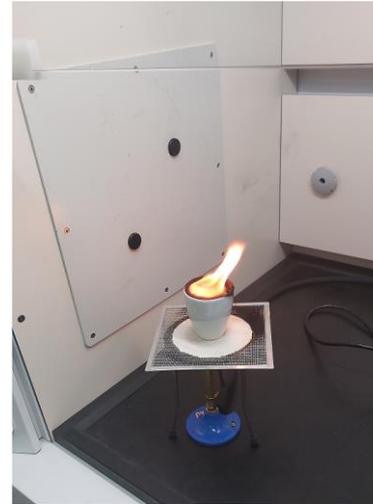
IMPROVEMENTS 2017-2021 - Laboratory for testing petroleum and petroleum products





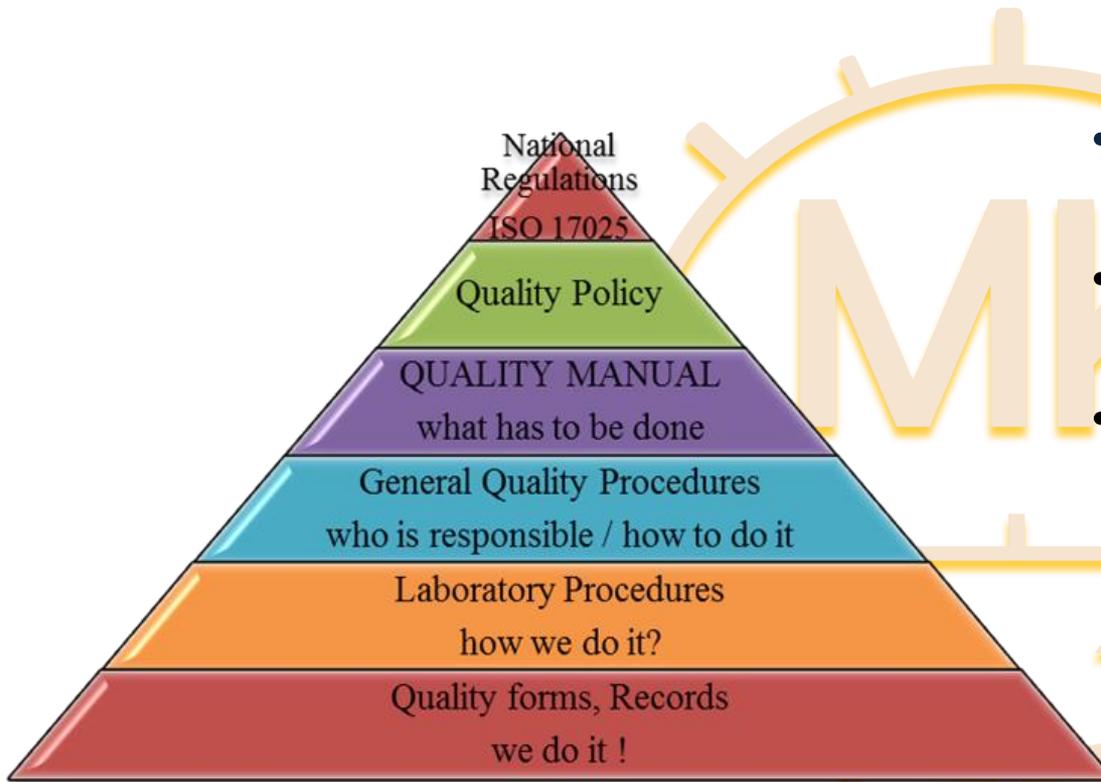
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IMPROVEMENTS 2017-2021 – Laboratory for testing petroleum and petroleum products – fuel oil





IMPROVEMENTS 2017-2021 QMS Documentation



- All QMS documents are reviewed at least once a year
- Quality Manual - version 8 issued in September 2020
- QMS covered 7 calibration laboratories (mass, pressure, volume and flow, temperature and humidity, AC/DC low frequency, acoustics, time and frequency) and 1 laboratory for testing petroleum and petroleum products)



IMPROVEMENTS 2017-2021 BoM`s QMS

MAIN CHANGES

2019 Peer-review of QMS according to ISO/IEC 17025:2017- EURAMET project N°1208 - Peer review of QMS and 3 laboratories - mass, volume&flow and temperature;

2020 Re-accreditation of the laboratories by NAB (pressure, AC/DC low frequency, relative humidity and acoustics);

2020 Initial accreditation of laboratory for testing petroleum and petroleum products (15 – teen testing methods) by NAB;

2021 Extension of the scope of accreditation in the field of time and frequency and increased 3 new methods for testing petroleum products



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS - PARTICIPATION IN ILCs

2017

Type of ILC/PT	Field/subfield	Pilot lab or provider of ILC/PT	Identification of ILC/PT	Parameters/ range of measurements	Status
ILC	Flow	INRIM	EURAMET 1395	Volume comparison at 20 L	Waiting for results
Research	Flow	EIM	EURAMET 1295	Guide on the calibration, operation and handling of micropipettes	Waiting for results
ILC	M	BEV	EURAMET.M.M-K4.2015 t.e. EURAMET 1346	Key comparison of 1 kg mass standards linked to CCM.M-K4	Measurements will be performed in March 2018

2018

Type of ILC/PT	Field/subfield	Pilot lab or provider of ILC/PT	Identification of ILC/PT	Parameters/ range of measurements	Status
EURAMET key comparison	M/mass	CMI	EURAMET 1300 / EURAMET.M.M-S7	Mass: 500 kg	Ongoing
EURAMET key comparison	M/mass	BEV	EURAMET 1346 / EURAMET.M.M-K4.2015 Key comparison of 1 kg mass standards linked to CCM.M-K4	1 kg mass standard, E1 class	Measurements made, Draft A is expected at the TC-M meeting in April 2019
Research	F/Flow	EIM	EURAMET 1295 Guide on the calibration, operation and handling of micropipettes	1 - 10 µL 10 - 100 µL 100 - 1000 µL 100 µL (constant volume)	Draft B

2019-2020

Type of ILC/PT	Field/subfield	Pilot lab or provider of ILC/PT	Identification of ILC/PT	Parameters/ range of measurements	Status
EURAMET key comparison	M/mass	CMI	EURAMET 1300 / EURAMET.M.M-S7 Comparison of 500 kg stainless steel standard	Mass: 500 kg	Ongoing
EURAMET key comparison	M/mass	BEV	EURAMET 1346 / EURAMET.M.M-K4.2015 Key comparison of 1 kg mass standards linked to CCM.M-K4	1 kg mass standard, E1 class	Final report
EURAMET key comparison	F/Flow	MIRS	EURAMET 1479/ EURAMET.M.FF-S14 Inter-comparison of 1000 L proving tank	1000 L	Ongoing
EURAMET comparison	T/Thermometry	FSB-LPM	EURAMET 1442 Comparison in the scope of EMPIR project HUMEA	Relative humidity from 10 %rh to 95 %rh at temperatures from -10°C to 50°C	Ongoing

2021

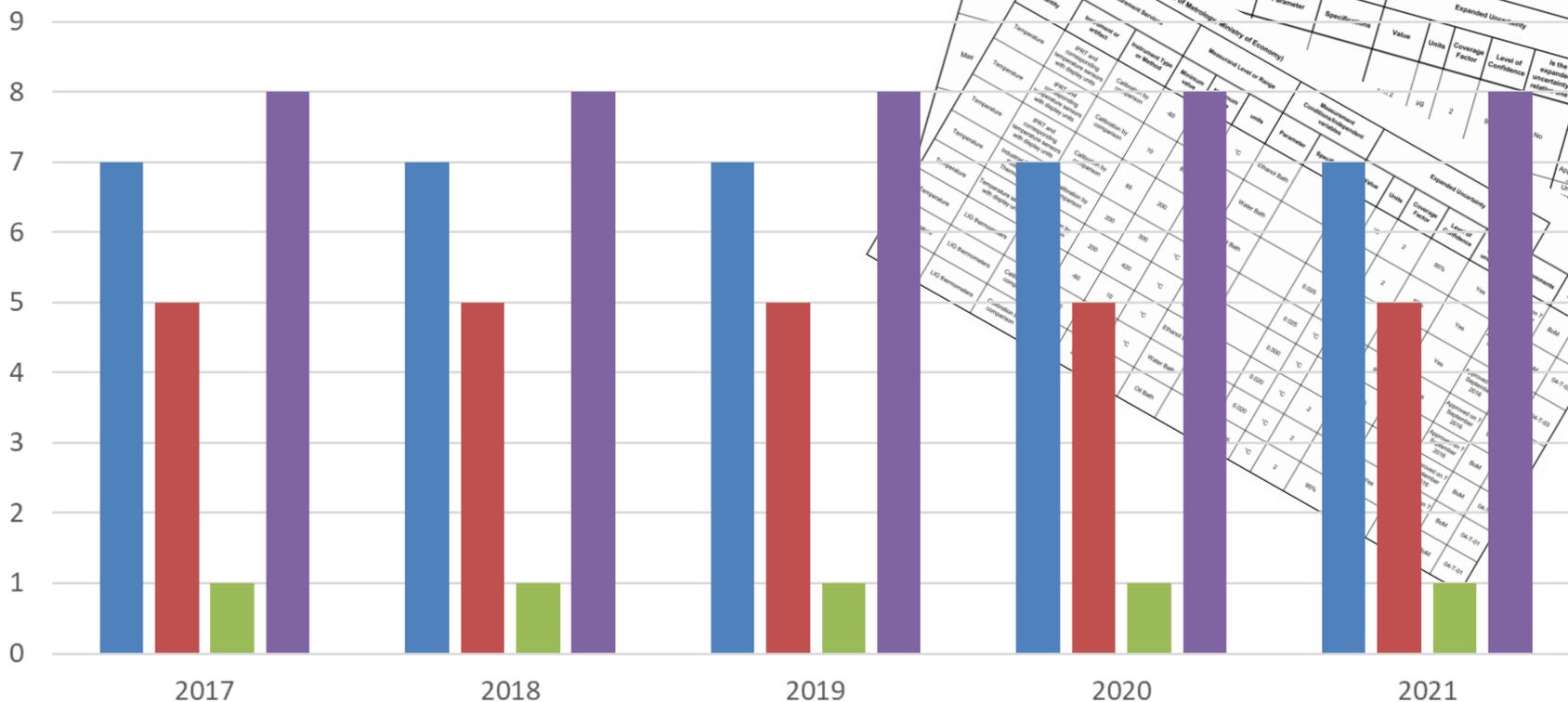
Type of ILC/PT	Field/subfield	Pilot lab or provider of ILC/PT	Identification of ILC/PT	Parameters/ range of measurements	Status
EURAMET key comparison	M/mass	CMI	EURAMET 1300 / EURAMET.M.M-S7 Comparison of 500 kg stainless steel standard	Mass: 500 kg	Final report published in July 2021
EURAMET key comparison	F/Flow	MIRS	EURAMET 1479/ EURAMET.M.FF-S14 Inter-comparison of 1000 L proving tank	1000 L	Ongoing
EURAMET comparison	T/Thermometry	FSB-LPM	EURAMET 1442 Comparison in the scope of EMPIR project HUMEA	Relative humidity from 10 %rh to 95 %rh at temperatures from -10°C to 50°C	Ongoing



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

CALIBRATION AND MEASUREMENT CAPABILITIES

■ Mass ■ Volume ■ Flow ■ Temperature



Mass and Related Quantities, Macedonia, The FYR of, BOM (Bureau of Metrology, Ministry of Economy)

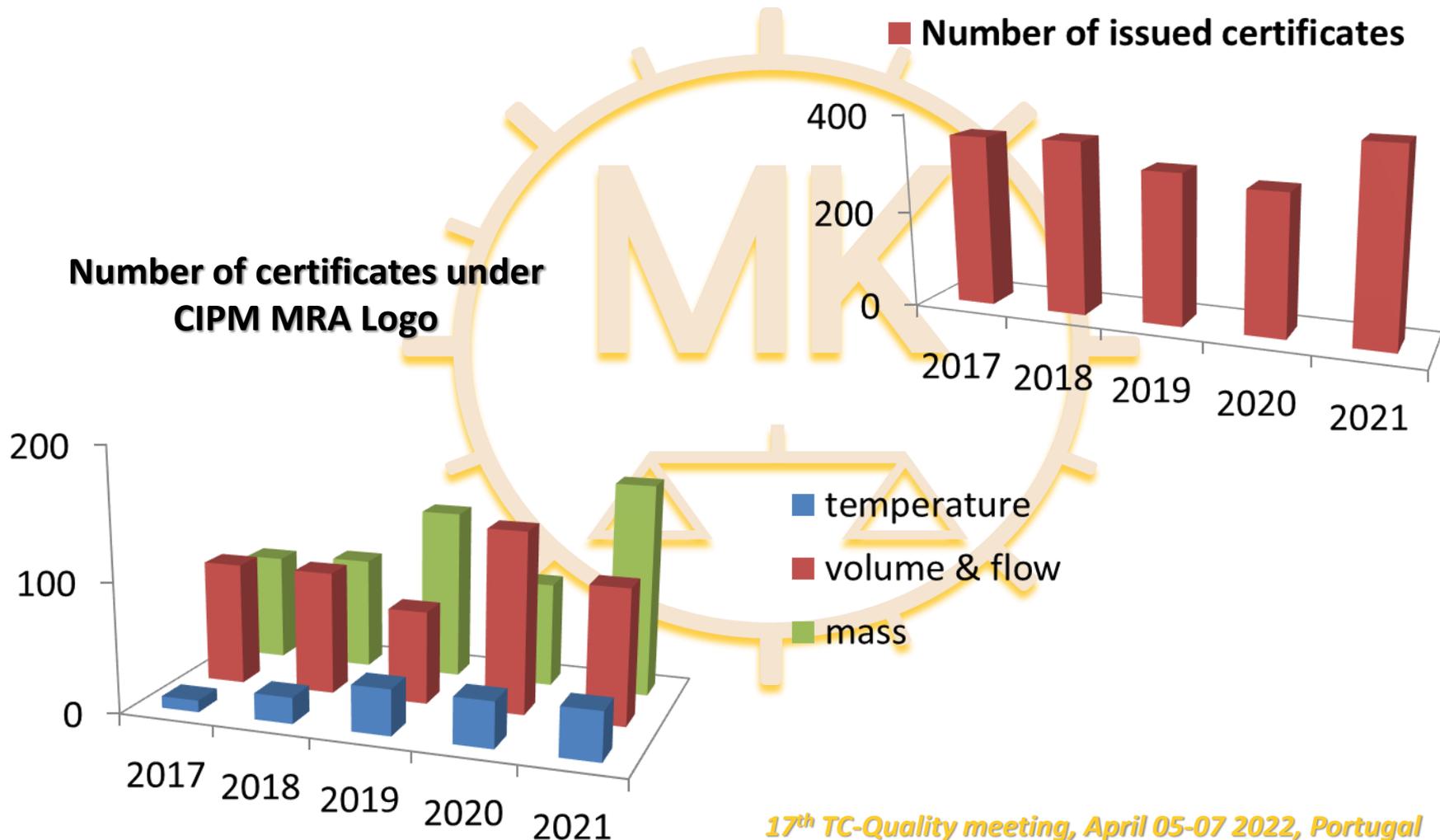
Quantity	Unit	Measurement Level or Range	Measurement Conditions/Independent Variable	Expanded Uncertainty
Mass	kg	0.1 - 1000	Normal	0.05%
Temperature	°C	0 - 1000	Normal	0.05%
Volume	l	0.1 - 1000	Normal	0.05%
Flow	l/min	0.1 - 1000	Normal	0.05%

2019 - extension the range of our CMC in the field of volume and flow

2019 - extension the range of our CMC in the field of volume and flow



IMPROVEMENTS - CALIBRATION CERTIFICATES





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IMPROVEMENTS 2017-2021 – SERVICE TO THE CUSTOMER

- ❑ Book of impressions
- ❑ Questionnaire - available on website / request for service evaluation
 - Collected from direct contact with customers
 - Contains elements related to quality of service, time for delivery of service, communication with staff, price and suggestions

БИРО ЗА МЕТРОЛОГИЈА ПРАШАЛНИК ЗА ЕВАЛУАЦИЈА (Evaluation Questionnaire)	GF 1-04-3 страна 1 of 1 Верзија 2 Август 2019
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Овој прашалник е наменет за оценување на услугата на Бирото за метрологија (БМ) кон клиентите. Целта на овој прашалник е континуирано подобрување на услугите на БМ кон клиентите. Во однос на тоа, Ви препорачуваме реално да ги изразите Вашите искуства, проблеми и забелешки, ако постојат, за да допринесете кон понатамошното следење и унапредување на услугите кои ги нуди Бирото за метрологијата.

КЛИЕНТ:	ДАТА:
---------	-------

Ве молиме, заокружете некое од подолу наведените алтернативи, во зависност од Вашето искуство според релевантните елементи од услугите овозможени од БМ.

бр.	Делови од услугите на Бирото за метрологија за кои се очекува оценка	Степен на оценка			
		одлично	Многу добро	добро	слабо
1	Калибрацијата и информацијата што сте ја добиле при барање на услуга на БМ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Тестирањето и информацијата што сте ја добиле при барање на услуга на БМ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Степенот на одговорност на БМ во Вашите барања за услуги	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Доверливост и транспарентност на понудите добиени од БМ за услуги	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Степенот на доверливост на мерните резултати добиени од БМ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Периодот потребен за комплетирање на услугата и повраток на опремата (од калибрација)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Техничката поддршка овозможена од БМ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Опишете ги, доколку сте ги имале, проблемите со кои сте се соочиле за време на соработката со БМ (доколку имате, ве молам прецизно наведете на што се однесуваат вашите забелешки - лабораторија, тип, активност) во однос на:

Организација
Време на реализација
Цена
Пристапност

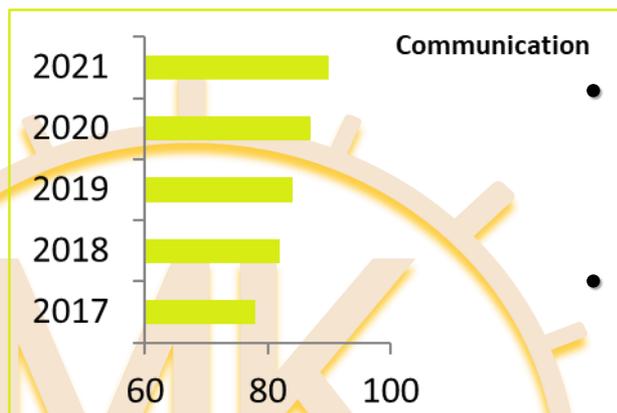
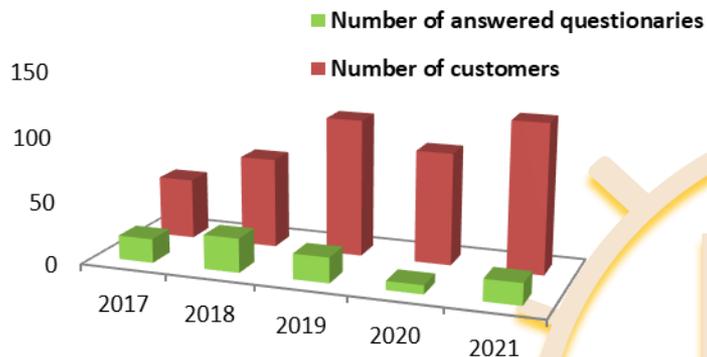
Предлози за усовршување (Ве молам, ако имате, наведете ги Вашите предлози за усовршување на услугите на БМ)

<input type="text"/>	
Име и презиме	Дата



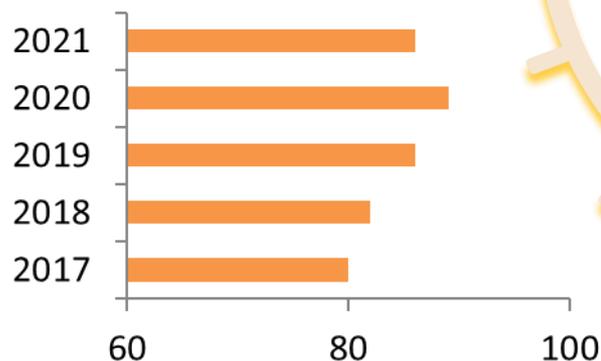
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IMPROVEMENTS 2017-2021 – SERVICE TO THE CUSTOMER

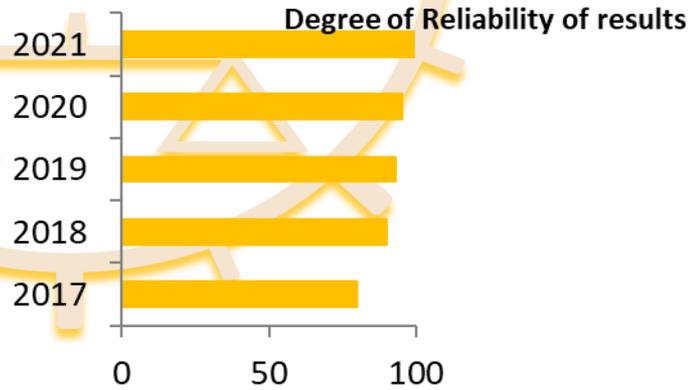


- Last two years, very low response – less than 15 %
- Customers in general satisfied from the services – more than 90%

Turnaround time



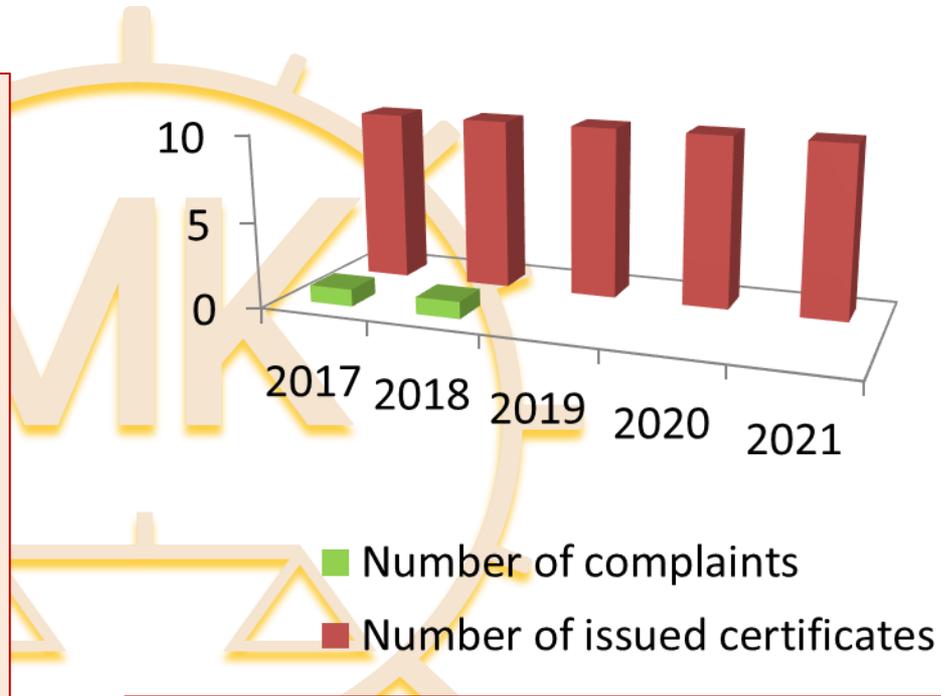
Degree of Reliability of results





IMPROVEMENT 2017-2021 - COMPLAINTS

- **Considered as one of the main sources of feedback on the quality of the calibration services**
- **“GP 1-07 Handling complaints from customer” - how to treat any complaint from the customer received in written or oral form**

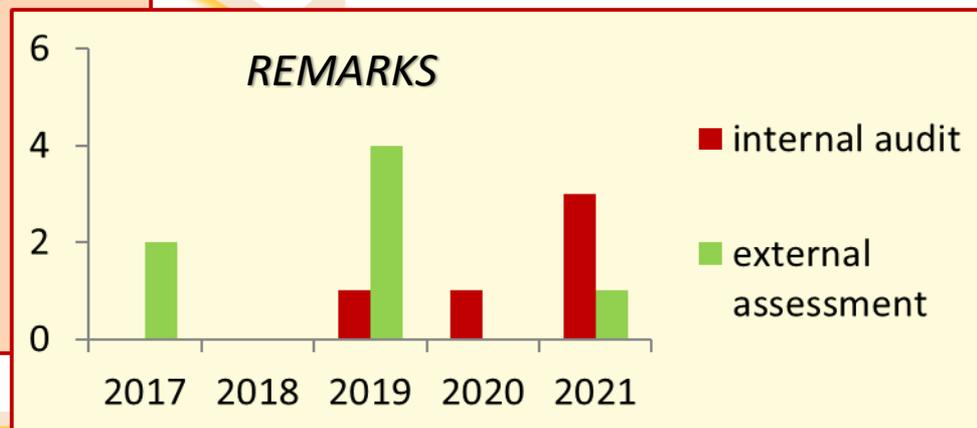
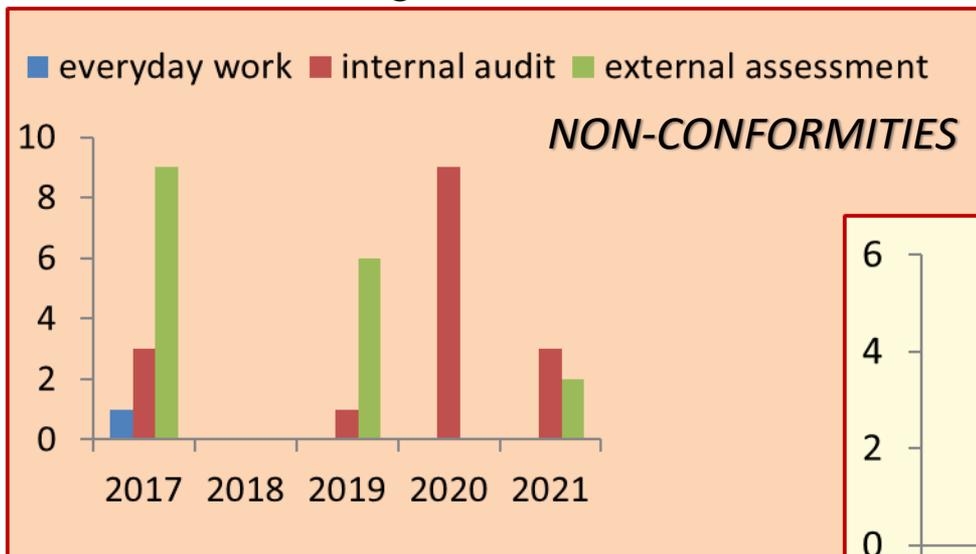


**Complaints generally referred to:
non-accredited services,
pricing and typing errors of certificates.**



IMPROVEMENTS 2017-2021 – NON-CONFORMING WORK

GP 1-08 Handling of non-conformities



Improvements in the process of the treatment non-conformities

- **Analysis of the reasons leading to non-conformity**
- **Clear definition of responsibilities for corrective/preventive actions**
- **Assessment of the efficiency**



IMPROVEMENTS 2017-2021 – INTERNAL AUDITS

GP 1- 11 INTERNAL AUDITS

- To detect any non-conformities or deviations from the written procedures and laboratory procedures during the calibration/testing and QMS implementation;
- To assess the effectiveness of the implementation of the QMS and its modalities in accordance with the requirements of the ISO/IEC 17025:2017;
- To produce outcome for continuous improvement of the QMS.

	2017	2018	2019*	2020	2021
Number of internal audits	8	8	9	9	9
Number of days duration of internal audits	8	8	9	9	9
Non-conformities	3	0	0	9**	3
Remarks/observations	0	0	1	1	3

* In 2019, focus was at transition to the new version of standards ISO/IEC 17025:2017

** NC were detected in new laboratory for testing petroleum products



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 – EXTERNAL ASSESSMENT

Identification of external audit action	Dates	Name of auditor(s) with university titles	NMI/DI	Qualifications
Accreditation				
Regular surveillance visit by NAB (IARNM) in the field of Quality management system, acoustic and electrical quantities	16 th of February, 2017	Mr. Dragan Veleovski	NAB (IARNM)	Lead assessor
		Mrs. Maja Aleksic	NAB (ATS-R. Serbia)	Technical assessor in the area of acoustic and vibration
		Mrs. Jelena Pantelic – Babic, PhD	DMDM-R. Serbia	Technical assessor in the area of electrical quantities
Regular surveillance visit by NAB (IARNM) in the field of Quality management system, pressure and	15 th and 16 th of November, 2017	Mr. Dragan Veleovski	NAB (IARNM)	Lead assessor
		Mr. Boris Ramac	DMDM-R. Serbia	Technical assessor in the area of mass and pressure
		Mrs. Slavica Simic	DMDM-R. Serbia	Technical assessor in the area of thermometry



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 – EXTERNAL ASSESSMENT

<p>Regular surveillance audit by NAB (IARNM) in the field of Quality management system, volume and flow, electrical quantities, acoustics</p>	<p>17th of May 2019</p>	<p>Mrs. Vida Zivkovic, MSc Mrs. Jelena Pantelic-Babic, PhD Mrs. Gordana Stefanovic Mrs. Ljiljana Micic</p>	<p>NAB (IARSM) DMDM-R. Serbia</p>	<p>Lead assessor – Former Director of DMDM (retired) Technical assessor in the area of electrical quantities (retired) Technical expert in the area of acoustic and vibration Technical assessor in the area of volume and flow</p>
<p>Re-accreditation surveillance audit by NAB (IARNM) in the field of QMS, pressure, humidity, electrical quantities and acoustics</p>	<p>27th and 28th of November 2019</p>	<p>Mrs. Vida Zivkovic, MSc Mrs. Jelena Pantelic-Babic Mrs. Gordana Stefanovic Mr. Boris Ramac Mrs. Slavica Simic</p>	<p>NAB (IARSM) DMDM-R. Serbia NAB (IARSM) DMDM-R. Serbia</p>	<p>Lead assessor Former Director of DMDM (retired) Technical assessor in the area of electrical quantities Technical expert in the area of acoustic and vibration Technical assessor in the area of pressure Technical assessor in the area of temperature and humidity</p>



Ministry of economy-Bureau of metrology Skopje, Republic of North Macedonia

IMPROVEMENTS 2017-2021 – EXTERNAL ASSESSMENT

		Peer review		
Peer review visit in the field of QMS, mass, temperature and volume&flow	14 th -15 th of November 2019	Mrs. Tamara Djekic Mrs. Ljiljana Micic Mrs. Slavica Simic Mr. Dragan Pantic	DMDM-R. Serbia	Quality manager of DMDM and TC-Q contact person Head of group for quantity of fluid in DMDM and TC-F contact person Head of group for temperature in DMDM and TC-T contact person Head of group for mass in DMDM and TC-M contact person
Regular surveillance audit by NAB (IARNM) at the Quality management system, electrical quantities, time & frequency and testing petroleum products	08 th and 09 th of April, 2021	Mrs. Vida Zivkovic, MSc Mrs. Jelena Pantelic-Babic, PhD Mr. Osman Sibonjic Mrs. Stanojla Obradovic	NAB (IARSM) IMBiH, Bosnia and Hercegovina NAB (IARSM)	Lead Assessor, Former Director of DMDM (retired) Technical assessor in the area of electrical quantities in DMDM (retired) Technical assessor for time & frequency Technical assessor for testing petroleum products (retired)



IMPROVEMENTS 2017-2021 – MANAGEMENT REVIEW

GP 1-12 MANAGEMENT REVIEW

Regular MR meeting - annual basis – always at the beginning of the year. Topics discussed:

- Suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Outcomes of recent internal audits;
- Status of corrective actions from internal and external audits;
- Assessment reports by external bodies;
- Results of inter-laboratory comparisons or proficiency tests;
- Changes inside in the laboratories;
- Customer and staff feedback;
- Analysis of the complaints;
- Identification of risks and proposals for improvement;
- Other relevant factors, such as quality control activities, calibration of equipment, resources and staff training.

The outcomes of the Management review meetings are a number of decisions, which directly or indirectly affect QMS.



RISKS

WEAK POINTS

- ✓ **Workload of staff**
- ✓ **Insufficient number of staff for some services**
- ✓ **Law on public servants**
- ✓ **Still not sufficient level of awareness on metrology**

STRONG POINTS

- ✓ **Qualified staff**
- ✓ **Openness and transparency**
- ✓ **Good results from ILCs/PTs**
- ✓ **Cooperation with IARSM, ISRSM, Universities**



OPPORTUNITIES - NEXT STEPS FOR IMPROVEMENT

- ✓ Upgrading e-DMS
- ✓ Submitting new CMCs
 - Relative humidity
 - Time & frequency
 - Pressure
- ✓ Expanding scope of measurements – gas flow, dimension, reference materials...



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