INSTITUTE FOR ACCREDITATION OF THE REPUBLIC OF NORTH MACEDONIA

Field and Scope of Accreditation of Conformity Assessment Bodies

PR 05-14

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1. PURPOSE

The purpose of this procedure, issued by the Director of the Institute for Accreditation of the Republic of North Macedonia (hereinafter: IARNM), is to unify the manner of displaying the fixed scope of accreditation in the annexes to the certificates of the conformity assessment bodies. The displaying of flexible scope together with assessment criteria are given the Procedure for accreditation of flexible scope, PR 05-09.

2. REFERENCE DOCUMENTS

ISO/IEC 17000: Conformity assessment. Vocabulary and general principles.
ISO/IEC 17011: Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
Standards of ISO 80000 series - from part 1 to part 14: Quantities and Units.
Global ACI-TECH-1-009 (M): GLOBAL ACI Policy for Measurement Uncertainty in Calibration
ILAC-G18: Guidelines for the formulation of Scopes of accreditation for Laboratories.
EA-2/15 M: EA Requirements for the Accreditation of Flexible Scopes
EA-4/02 M: Evaluation of the Uncertainty of Measurement in Calibration.
EA-4/17 M: EA Position Paper on the description of scopes of accreditation of medical laboratories
EA 1/22 A: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members
МКС EN ISO/IEC 17025:2018
JCGM 100:2008, GUM 1995 with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement. Вклучува и водичи за Evaluation of measurement data (Достапен на https://www.bipm.org/en/publications/guides/)
МКС EN ISO/IEC 17065:2012 Conformity assessment — Requirements for bodies certifying products, processes and services
МКС EN ISO/IEC 17067:2013 Conformity assessment — Fundamentals of product certification and guidelines for product certification scheme

3. GUIDELINES FOR TESTING LABORATORIES

The scope of activities of the testing laboratories that require accreditation is stated in the Application for Testing Laboratory Accreditation OB 05-22-1. By filling in the relevant tables, the applicant shall indicate the scope for which they are seeking accreditation and which will be, after granting the accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the accreditation certificate OB 05-25.

Sample table showing the scope of accreditation of a testing laboratory:

Подрачје на тестирање (класификација според ИАРСМ Правилникот Р 15): ***Field of testing (classification according to IARNM Regulation R15):***					
□ фиксен опсег ***(fixed scope)***		**□ флексибилен опсег** ***(flexible scope)***		**□ фиксен / флексибилен опсег** ***(fixed/flexible scope)***	
Напомена: Со „*“ се обележува флексибилниот опсег	Степен на флексибилност (според процедурата ПР 05-09): *Degree of flexibility (according Procedure PR 05-09):*				
	□ нови ажурирани верзии на стандарди/ документи ***new up-date versions of the standards/ documents***	**□ нови материјали/производи/предмети и/или карактеристика/својство/аналит кој се мери и/или проширување на мерниот опсег** ***new materials/ products/ items and/or measured characteristic/ property/ analyte, and/or extension of measuring scope***		**□ нови стандарди/документи, прилагодени на барањата на клиентот** ***new standards/ documents, upon a request by the client***	
Бр.	**Ознака на** стандардната метода, нестандардната метода, метода развиена во лабораторија, метода специфицирана од страна на производителот на опремата, метода објавена од угледна техничка институција или метода објавена во релевантни научни трудови или весници ***Reference to** standard testing method, nonstandard testing method, method developed by the laboratory, method specified by the manufacturer of the*	**Наслов на** стандардната метода, нестандардната метода, метода развиена во лабораторија, метода специфицирана од страна на производителот на опремата, метода објавена од угледна техничка институција или метода објавена во релевантни научни трудови или весници ***Title of** standard testing method, nonstandard testing method, method developed by the laboratory, method specified by the manufacturer of the*	**Подрачје (r)** на мерење, тестирање ***Range (r)** of measurement, testing*	**Материјали односно производи** ***Materials /Products***	**честота** ***frequenc***

No.	*equipment, method published by reputable technical organization or method published in relevant scientific texts or journals*	*equipment, method published by reputable technical organization or method published in relevant scientific texts or journals*			***y***

Instructions for filling in the table:

The gray part of the table clearly and unambiguously defines each field of testing (according to the IARNM Rulebook, R 15) with numbers and letters. If the laboratory applies for accreditation in a field that is not specified in the IARNM Rulebook, R 15, then that field is defined under the item "other", where it is clearly and unambiguously described. Also in the gray part of the table the type of accreditation scope is stated, fixed, flexible or if the scope is a combination of fixed and flexible methods, fixed/flexible scope is stated in the type of scope. The degree of flexibility according to the IARNM procedure, PR 05-09 must also be stated. The flexible scope is clearly marked with the symbol "*" in the first column next to the ordinal number of the test method.

Column 1:

The ordinal numbers of the test methods are entered in the first column of the table. The numbers are placed sequentially throughout the scope, with each method being uniformly denoted (do not start every table with the number 1 from the beginning). In this column the "*" indicates the flexible scope next to the ordinal number of the test method.

Column 2:

The **second column** presents clearly and precise the reference of the method used, i.e. standard method, non-standard method, laboratory method, method specified by the equipment manufacturer, method published by a reputable technical institution, or method published in relevant scientific journals. The name and the reference of the relevant law or bylaw, manufacturer instruction, scientific paper, textbook or other recognized sources, also shall be stated if relevant. In case of standard method and fixed scope, in addition to the standard method reference, the year of the edition must be stated whereby the laboratory must use the latest edition. When the method is specified by the equipment manufacturer, the name/type of the equipment shall be specified, a reference to the appropriate laboratory instruction describing the test procedure, and the status of its revision (if necessary).

Column 3:

The **third column,** which correspondents with the second column, lists the original title of the standard method, non-standard method, method developed in the laboratory, method specified by the equipment manufacturer, method published by a reputable technical institution or the method published in relevant scientific journals. In this column the title of the testing technique (where appropriate) and the title of the parameter tested, shall be stated.

Column 4:

The **fourth column** for each method / technique / parameter lists the measurement range.

The manner in which the measurement range is written is as follows:

1. The lower limit of the scope is written with a number that contains the SI - unit of measurement, then it is separated by the sign "÷" or with "-", and then the upper limit of the scope is written with a number that is accompanied by the SI unit of measurement, or the upper and lower limit separated by parentheses and accompanied by the unit of measurement.

Example: 0,010 mg/L ÷ 0,500 mg/L, or (0 - 100) g/100g.

2. The following rule must be observed: Value - space - symbol of the unit of measurement

- This rule also applies to the percentage sign (%)
- There is an exception for the symbols for plane angle, minutes and seconds (°, ′ and ″), when there is no space, ie: value - symbol for unit of measurement.

3. Decimal numbers are written with a comma ",".

4. All units of measurement shall be expressed in SI units, and if they are not, they shall be converted and expressed in SI units if possible. In cases where this is not possible, the justification for such an expression shall be supported by reference documents where units other than the SI system are given.

5. The symbols of the units of measurement are written in Latin or Greek alphabet (Ω and μ), roman letters - italic letters are used for sizes (eg *m* for mass).

6. The symbols of the units of measurement are written in lower case ("m", "s", "mol"), except when they are derived from the name of a person (eg unit of pressure named after the scientist Blaise Pascal - "Pa") .

- Exception is the "liter" sign - it is recommended to use a capital "L".

7. Symbols of derived units formed by division are displayed with a sign (/), or as a negative degree. Example: g/L or $g \cdot L^{-1}$.

8. In the expression of the measuring units it is necessary to use the SI-prefixes in accordance with the Rulebook on definitions, names and symbols, field and manner of application, obligation for use and manner of writing legal measuring units ("Official Gazette of the Republic of Macedonia", No. 104/2007). This means that measuring scopes are not expressed in numbers with more than three digits. Example: 20 mg ÷ 100 kg, and not 20 mg ÷ 100 000 mg.

Column 5:

The **fifth column** lists the **materials or products** to be tested.

Column 6:

The **sixth column** lists the "**frequency**" (F) with which the tests are performed: (D) daily; (WEEK) once or several times a week; (M) per month; (P) periodically or several times a year.

Practical examples: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Подрачје на тестирање (класификација според ИАРСМ Правилникот Р 15)/ *Field of testing (classification according to IARNM Regulation R15):*
3. Хемија/ *Chemistry*
8. Микробиологија/ Microbiology

Класификација по тип на производи/материјали за тестирање/ *Classification according to types of poducts/materials for testing*
6.1 Вода/ *Water*
7.8 Вода /*Waters*
7. Храна/ *Foodstuffs*
18.1 Добиточна храна/ *Feed*
17.1 Фармацевтски препарати/ *Pharmaceuticals*
20. Друго/ *Others (*брисеви од работни површини и трупови на заклани животни/ *swabs from working surfaces and surfaces from carcasses)*

□ фиксен опсег ***(fixed scope)***	**□ флексибилен опсег** ***(flexible scope)***	**√□ фиксен / флексибилен опсег** ***(fixed/flexible scope)***

Напомена: Со „*“ се обележува флексибилниот опсег	Степен на флексибилност (според процедурата ПР 05-09): *Degree of flexibility (according Procedure PR 05-09):*		
	√□ нови ажурирани верзии на стандарди/ документи ***new up-date versions of the standards/ documents***	**√□ нови материјали/производи/предмети и/или карактеристика/својство/аналит кој се мери и/или проширување на мерниот опсег** ***new materials/ products/ items and/or measured characteristic/ property/ analyte, and/or extension of measuring scope***	**□ нови стандарди/документи, прилагодени на барањата на клиентот** ***new standards/ documents, upon a request by the client***

Бр. ***No.***	**Ознака на** стандардната метода, нестандардната метода, метода развиена во лабораторија, метода специфицирана од страна на производителот на опремата, метода објавена од угледна техничка институција или метода објавена во релевантни научни трудови или весници ***Reference to** standard testing method, nonstandard testing method, method*	**Наслов на** стандардната метода, нестандардната метода, метода развиена во лабораторија, метода специфицирана од страна на производителот на опремата, метода објавена од угледна техничка институција или метода објавена во релевантни научни трудови или весници ***Title of** standard testing method, nonstandard testing method, method developed by the laboratory, method specified*	**Подрачје (r)** на мерење, тестирање ***Range (r) of** measurement, testing*	**Материјали односно производи** ***Materials /Products***	**честота** ***freq***

	developed by the laboratory, method specified by the manufacturer of the equipment, method published by reputable technical organization or method published in relevant scientific texts or journals	*by the manufacturer of the equipment, method published by reputable technical organization or method published in relevant scientific texts or journals*			***u e n c y***
1.	МКС EN ISO 16266:2006	Детекција и броење на *Pseudomonas aeruginosa* - Метод со мембранска филтрација *Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration*		вода *water*	Д *D*
2.	МКС EN ISO 6461-2:1986	Детекција и броење на спори од сулфиторедуктивни бактерии (клостридии), Дел 2: Мембранска филтрација *Water Quality-Detection and enumeration of the spores of sulphite reducing anaerobes (clostridia), Part 2: Membrane filtration*		вода *water*	Д *D*
3.	МКС EN ISO 21528-2:2004	Хоризонтални методи за детекција и броење на *Enterobacteriaceae* Дел 2: Метод на броење на колонии *Horizontal methods for the detection and enumeration of Enterobacteriaceae Part 2: Colony-count method*		храна и храна за животни, брисеви од работни површини и трупови на заклани животни *food and animal feed, swabs from working*	Д *D*

				surfaces and surfaces from carcasses	
4.	МКС EN ISO 937:1978	Месо и производи од месо – определување на содржина на азот (Kjeldahl метод) *Meat and meat products- Determination of nitrogen content (Kjeldahl method)*	Опсег/Scope: (0 ÷ 10) g/100 g	месо и производи од месо *meat and meat product*	НЕД *W*
5.*	МКS EN 15662:2011 AOAC 2007.01:2007	Остатоци на пестициди во храна со екстракција/ партиционирање со ацетонитрил и матрикс дисперзивна SPE (LC-MS-MS детекција)(2) *Pesticide residues in foods by acetonitrile extraction/ partitioning and matrix dispersive SPE (LC-MS-MS detection)*(2)	Опсег/Scope: 0,010 mg/L ÷ 0,500 mg/L	-храна со висока содржина на масти -храна со ниска содржина на масти(2) *-food with high fat content* *-food with low fat content*(2)	НЕД W
6.*	Ph. Eur. Валидирани аналитички методи од производителот(1)	Монографии и методи пропишани во Европска фармакопеја Спецификации и валидирани аналитички методи од документација на производителот за фармацевтските препарати. Со примена на следниве техники: - pH – метрија - јонометрија - гравиметрија - титриметрија - тест на растворливост (апарат за растворливост) - тест за распадливост (апарат за распадливост) - UV/VIS спектрофотометрија - хроматографија на тенок слој (TLC) - гасна хроматографија (GC/FID/ECD) и Headspace техника - високо ефикасна течна хроматографија (HPLC/ DAD/FLD/RID/MS-MS) - кондуктометрија		Фармацевтски препарати: - суро вини - фарм ацевтски дозирани форми, пропишани во Ph.Eur.(2)	

		- рефрактометрија - полариметрија - Атомска апсорпциона спектрометрија (AAS) Физички и хемиски испитувања (соодветно за препаратот) - изглед - бистрина на раствор - боја на раствор - pH - концентрација на јони во раствор - губиток со сушење - содржина на вода - остаток по испарување - сулфатен пепел - вкупен пепел - големина на честици - индекс на рефракција - специфична оптичка ротација - идентификација - определување на содржина - воедначеност на дозирани единици - растворливост на активна компонента - рападливост на цврсти дозирни форми - киселински број - естерски број			

		- пероксиден број - хидроксилен број - јоден број - сапунификационен број - несапунливи материи - спроводливост на вода - одредување на елементи			
	Ph. Eur. Validated analytical methods from the manufacturer(1)	*Monographs and methods described in European Pharmacopoeia (Ph.Eur.).* *Specifications and validated analytical methods from the manufacturer's documentation of the pharmaceuticals.* *Using the following techniques:* *- potentiometric determination of pH* *- gravimetric techniques* *- titrimetric techniques* *- dissolution test (dissolution apparatus)* *- disintegration test (disintegration apparatus)* *- UV/VIS spectrophotometry* *- thin layer chromatography (TLC)* *- gas chromatography (GC/FID/ECD) & Headspace* *- high performance liquid chromatography (HPLC/ DAD/FLD/RID/MS-MS)* *- conductometry* *- refractometry* *- polarimetry* *- AAS spectrometry* *Physical and Chemical tests (as appropriate to product)*		*Pharmaceuticals: raw materials - pharmaceutical dosage forms, as described in Ph.Eur(2)*	

		- *appearance* - *clarity of liquids* - *colour of liquids* - *solubility* - *pH* - *ion concentration* - *loss on drying* - *content of water* - *residue on evaporation* - *sulphate ash* - *total ash* - *particle size* - *refractive index* - *specific optical rotation* - *identification* - *assay* - *uniformity of dosage units* - *dissolution of active ingredient* - *disintegration of solid dosage forms* - *acid value* - *ester value* - *peroxide value* - *hydroxyl value* - *iodine value* - *saponification value* - *unsaponifiable matter*			

		- *conductivity of water* - *determination of elements*			
7.	Упатство на производителот mini VIDAS, BioMerieux СОП XXX, верзија 1	Детекција на L. Monocytogenes *Detection of L. Monocytogenes*		Храна и храна за животни *Food and feed*	П *P*

*

(1) It is hereby allowed to introduce new versions of standards/ methods, procedures for examination in a rapidly evolving area.
(2) It is allowed to introduce additional materials/products/items for testing/ examination within the limits of application of the method, and/or characteristic/ property/ parameter that is measured/ tested

4. GUIDELINES FOR MEDICAL LABORATORIES

The scope of activities of medical laboratories that require accreditation is stated in the Medical Laboratory Accreditation Application OB05-33. By filling in the relevant tables, the applicant shall indicate the scope for which they are seeking accreditation and which will be, after granting accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the accreditation certificate OB 05-33-4 (the Annex according to МКС EN ISO 15189:2022.

Sample table showing the scope of accreditation of a medical laboratory in Annex OB 05-33-4:

Класификација по подрачја за областа на тестирање според ИАРСМ Правилник Р 15/ *Classification according to testing areas given in IARNM Regulation R 15* _____ Класификација по тип на производи/материјали за тестирање според ИАРСМ Правилник Р 15/ *Classification according to types of products/materials for testing given in IARNM Regulation R 15* _____			
☐ фиксен опсег (fix scope)		**☐ флексибилен опсег (flexible scope)**	**☐ фиксен / флексибилен опсег (fix/flexible scope)**
Напомена: Со „*“ се обележува флексибилни от опсег	Степен на флексибилност (според процедурата ПР 05-09): *Degree of flexibility (according to Procedure PR 05-09):*		
	☐ промена на опрема/ метод/ процедура за испитување changing of equipment/ method/ examination procedure	**☐ додавање на нови аналити/ параметри/ карактеристики кои се испитуваат addition of new analytes/ parameters/ characteristics for examination**	**☐ додавање на нови материјали/ матрикси за испитување addition of new materials/ matrixes for examination**

Бр. ***No.***	**Опрема/ Метод/ Референца на процедурата за испитување** ***Equipment/ Method/ Reference to examination procedure***	**Техника** **Technique**	**Аналит/ Параметар** ***Analyte/ Parameter***	**Материјал/ Матрикс за испитување** ***Material/ Matrix for examination***
I. Се пополнува доколку телото за оцена на сообразност во својот состав има повеќе лаборатории (или локации)				
II. Се пополнува доколку телото за оцена на сообразност во својот состав има повеќе лаборатории (или локации)				

Instructions for filling out the table:

In the grey part of the table, indicate the classification by field and type of testing product/material according to IARNM Regulations R 15 (use the classification for testing laboratories and medical laboratories, point 2). If you specify "other", please write what it refers to and where it belongs.

Select whether the scope is fixed, flexible, or fixed/flexible, as well as the degree of flexibility, according to IARNM Procedure PR 05-09. For a flexible scope, mark it with "*" the sequence number of activities with a flexible scope that you have listed sequentially in the table.

Correctly list in individual tables the examination you perform in the laboratory, as well as those performed on site, i.e. at the temporary location of the laboratory. Mark it on each table (copy the table as many times as you need). If the laboratory has multiple locations, the scope for each location shall be clearly identified.

Input of examination activities (methods/procedures) from the accreditation scope:

Enter the data so that each examination method/parameter (analyte) is entered in a single row of the table. Add as many rows as you need.

In **the first column** of the table are the current numbers of the examination methods. Put the numbers across the entire scope so that the method is uniquely labelled (do not start each table with the number 1 at the beginning). In this column, with "*" label the flexible scope next to the ordinal number of the test method.

The second column describes the method (procedure) of the examination. When a method is specified by the equipment manufacturer, the name/type of equipment (including the code version) and a reference to the appropriate laboratory instruction (or procedure) describing the examination procedure or designation and version of the test kit shall be specified. When a method is defined according to an international standard method, a non-standard method, a method developed in a laboratory, a method published by a reputable technical institution, or a method published in relevant scientific journals, the source document (or citation of the paper) and a reference to the relevant laboratory manual (or procedure) describing the examination procedure and the status of version/revision of the document shall be clearly stated. If you are using any modified procedure, it shall be marked "modified".

The third column lists the technique, i.e. the type or principle of the test method used. If an abbreviation is given (e.g. ECLIA), a disambiguation of the abbreviation, i.e. the full name of the abbreviation, must be provided at the end of the table.

The fourth column lists the parameters, i.e. analytes or characteristics that are examined by the appropriate method/technique.

The fifth column lists the material, i.e. the matrix being examine

Practical examples: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Класификација по подрачја за областа на тестирање според ИАРСМ Правилник Р 15/ *Classification according to testing areas given in IARNM Regulation R 15*

Класификација по подрачја за областа на тестигање/ Classification according to testing areas
2. Биологија, Биохемија/Biology, biochemistry
2.4 Ензимски тестови/ Enzyme tests
3. Хемија/ Chemistry
3.1 Физичко-хемиски методи/ Physicochemical methods
3.2 Класични методи за анализа/ Conventional method of analyses
7. Механичко тестирање/ Mechanical testing
7.3 Микроскопско тестирање/ Microscopic testing

Класификација по тип на производи/материјали за тестирање според ИАРСМ Правилник Р 15/ *Classification according to types of products/materials for testing given in IARNM Regulation R 15*
1. Биолошки примероци /Biological samples
1.1 Клинички и патолошки примероци/ Clinical and pathological samples

♦ **фиксен опсег (fix scope)**	□ **флексибилен опсег (flexible scope)**	□ **фиксен / флексибилен опсег (fix/flexible scope)**

Напомена: Со „*“ се обележува	Степен на флексибилност (според процедурата ПР 05-09): *Degree of flexibility (according to Procedure PR 05-09):*

флексибилни от опсег	☐ **промена на опрема/ метод/ процедура за испитување** **changing of equipment/ method/ examination procedure**	☐ **додавање на нови аналити/ параметри/ карактеристики кои се испитуваат** **addition of new analytes/ parameters/ characteristics for examination**	☐ **додавање на нови материјали/ матрикси за испитување** **addition of new materials/ matrixes for examination**

Бр./ ***No.***	**Опрема/ Метод/ Референца на процедурата за испитување** ***Equipment/ Method/ Reference to examination procedure***	**Техника / Technique**	**Аналит/ Параметар** ***Analyte/ Parameter***	**Материјал/ Матрикс за испитување** ***Material/ Matrix for examination***
Име на лабораторијата и локација/ адреса				
1.	Автоматски хематолошки бројач Mindray BC-30s СОП хххх *Automatic Hematology counter* *Mindray BC-30s*	AEIC (Automatic electric impedance for counting) CALC (Пресметка)		Полна крв/ Whole blood
		AEIC	Леукоцити / Leukocytes	
		AEIC	Еритроцити/ Erythrocytes	
		PHO	Хемоглобин/ HGB	
		CALC	MCV (Mean cell volume)	
		CALC	HCT (Hematocrit)	
		AEIC	Тромбоцити/ PLT	
2.	Автоматски хематолошки бројач Mindray BC-30/ *Automatic Hematology counter* *Mindray BC-30* СОП хххх	*AEIC (Automatic electric impedance for counting)* *CALC (Пресметка)*		Полна крв/ Whole blood
		AEIC	Леукоцити / Leukocytes	
		AEIC	Еритроцити/ Erythrocytes	
		PHO	Хемоглобин/ HGB	
		CALC	MCV (Mean cell volume)	
		CALC	HCT (Hematocrit)	
		AEIC	Тромбоцити/ PLT	

3.	Седиментација на еритроцити/ *Sedimentation rate of erythrocytes* СОП ххххх	*Вестергрен метода -мерење на плазматски столб на градуирана скала / Westergren method*		Цитратна полна крв/ *Citrate whole blood*
4.	Уриноанализатор DocUReader 2 Pro/ *Urinalysis on DocUReader2 Pro* СОП хххх	*Макроскопски опис и мултипараметарски уринарни тест ленти/ Macroscopic and multiparametar dip-stick urinalysis* *macroscopic (MAC) dip-stick (DS)*		Урина/*Urine*
		MAC	Изглед/ Appearance	
		MAC	Боја/ Colour	
		DS	Специфична тежина/ Specific gravity	
		DS	pH	
		DS	Глукоза/Glucose	
		DS	Билирубин/ Bilirubin	
		DS	Кетони/Ketones	
		DS	Еритроцити/ Erythrocytes	
		DS	Леукоцити/ Leukocytes	
		DS	Протеини/ Proteins	
		DS	Уробилиноген/ Urobilinogen	
		DS	Нитрити/ Nitrites	
4.	Микроскопско испитување на седимент на урина/*Microscopic examination of the urinary sediment* СОП ххх	*Микроскопирање/ MIC (microscopic)*	Седимент на урина/ Urine sediment (MIC)	Урина/ *Urine*
			Леукоцити/ Leukocytes	
			Еритроцити/ Erythrocytes	
			Епителни клетки/ Epithelial cells	

			Хијалински цилиндри/ Hyaline casts	
			Гранулирани цилиндри/ Granular casts	
			Бактерии/ Bacteria	
			Кристали/Crystals	
5.	Биохемиски анализатор Architect c4000/ *Biochemical analyzer Architect c4000* СОП xxx СОП xxx СОП xxx СОП xxx	*Фотометриски методи / Photometric methods (PHO)*		Серум/ *Serum*
		PHO	Глукоза/Glucose	
		PHO	Вкупен холестерол/ Total cholesterol	
		PHO	Триглицериди/ Triglicerides	
		PHO	Уреа / Urea	
		PHO	Креатинин/ Creatinine	
		PHO	АСТ (Аспартат аминотрансфераза)/ AST (Aspartate aminotransferase)	
		PHO	АЛТ (Аланин аминотрансфераза)/ ALT (Alanine aminotransferase)	
		PHO	Серумско железо/ Iron	

5. GUIDELINES FOR CALIBRATION LABORATORIES

The scope of activities of the calibration laboratories that require accreditation is stated in the Application for Calibration Laboratory Accreditation OB 05-02. By filling in the relevant tables, the applicant shall indicate the scope for which they are seeking accreditation and which will be, after granting accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the accreditation certificate of the calibration laboratory OB05-32.

** The scope of accreditation shall be in accordance with Global ACI-TECH-1-009, item 4.*

Калибрациска и мерна можност (Calibration and Measurement Capability) - CMC
Подрачје (од ИАРСМ документот Р 15) / *Field (from the IARNM document R 15):*
Локација каде се изведува калибрацијата:

Реден број No.	Предмет на калибрација *Subject of calibration*	Мерен опсег Measuring range	Мерна неодреденост *Measurement uncertainty**	Метода на калибрација *Method of calibration*	Забелешка Remark
1	2	3	4	5	6

Calibration and measurement capability (CMC) is mandatory element of the scope of calibration laboratory, expressed in terms of: measurand or reference material, calibration or measurement method or procedure and type of instrument or material to be calibrated or measured, measurement range and additional parameters where applicable, and measurement uncertainty (as given in OB 05-32).

Before filling the columns in the table, by which the calibration and measurement capability is expressed, the field (physical quantity) and the corresponding sub-field in accordance with P 15 "Rulebook for determining the fields for calibration, testing, inspection and certification areas" shall be stated, without the ordinal number of the field / sub-field.

In the field "Location where the calibration is performed" the following is stated: "in the laboratory", "on site", etc.

Instructions for filling the table:

Column 1 "Ordinal number": In this column, the ordinal numbers for each measuring range are filled in sequentially.

Example 1:

Калибрациска и мерна можност (Calibration and Measurement Capability) - CMC					
Димензионални големини / Должина *Dimensional quantities / Length*					
Локација каде се изведува калибрацијата:					
Реден број No.	Предмет на калибрација *Subject of calibration*	Мерен опсег Measuring range	Мерна неодреденост *Measurement uncertainty**	Метода на калибрација *Method of calibration*	Забелешка Remark
	Линеали / *Rulers*				
1		0 mm ÷ 200 mm			
2		200 mm ÷ 500 mm			
3		500 mm ÷ 2000 mm			

Column 2 "Subject of calibration (meters to be calibrated)": This column lists the types of measuring instruments that have common characteristics in terms of measurement size. To define the attachment more precisely, the types of measuring instruments shall be described and named in sufficient detail to give a clear meaning for which measuring instruments the laboratory has the capacity to calibrate. The name in Macedonian is written in roman letters while the English translation is written in italics.

Example 2:

Калибрациска и мерна можност (Calibration and Measurement Capability) - CMC					
Димензионални големини / Должина *Dimensional quantities / Length*					
Локација каде се изведува калибрацијата:					
Реден број No.	Предмет на калибрација *Subject of calibration*	Мерен опсег Measuring range	Мерна неодреденост *Measurement uncertainty**	Метода на калибрација *Method of calibration*	Забелешка Remark
	Линеали / *Rulers*				
1		0 mm ÷ 200 mm	0,6 µm+4,5x10^{-6} L		L – измерената должина (во мерна единица како во мерниот опсег) L – measured length (in measurement unit as in the measuring range)
2		200 mm ÷ 500 mm	2,5 µm+4,5x10^{-6} L		
3		500 mm ÷ 2000 mm	3,1 µm+4,5x10^{-6} L		
	Мерни ленти / *Tape measures*				
4		0 mm ÷ 5 m	3,1 µm+4,5x10^{-6} L		L – измерената должина (во мерна единица како во мерниот опсег) L – measured length (in measurement unit as in the measuring range)
5		5 m ÷ 30 m	21 µm		

Column 3 "Measuring range": This column lists the measuring range of the measuring instruments for which the laboratory has the capacity to perform the calibration. In case the measuring instruments have several ranges, or it is a set of measuring instruments with different ranges, it is necessary to specify the lower limit of the lowest range and the upper limit of the highest range. Analogously, for a set of unit values (resistors, weights, etc.) the measuring range is expressed by stating the lowest nominal value and then the highest nominal value. Measuring ranges are written as follows:

1. The lower limit of the range is written with a number that contains SI - unit of measurement, then it is separated by the sign "÷", and then the upper limit of the range is written with a number that is accompanied by the SI unit of measurement.

Example 3:20 mg ÷ 100 mg.

2. In the expression of the measuring units it is necessary to use the SI-prefixes in accordance with the Rulebook on definitions, names and symbols, field and manner of application, obligation for use and manner of writing legal measuring units ("Official Gazette of the Republic of Macedonia", No. 104/2007). This means that measuring ranges are not expressed in numbers with more than three digits.

Example 4: 20 mg ÷ 100 kg, and not 20 mg ÷ 100 000 mg.

3. If the measuring range consists of two ranges that refer to two different sizes that characterize the measuring signal, first the range for which the data given in column 4 refers

to is written and then in parentheses the range of the second size is written. Such are the ranges of alternating voltage, alternating current, power, etc.

4. If the measuring range consists of multi-series continuous measuring ranges with common calibration points (lower and upper limits), where applicable, the continuous ranges shall be displayed clearly and accurately whereby the upper limit of the range must represent the lower limit of the successive continuous range. Subsequently, the accompanying measurement uncertainty within multi-series continuous measurement ranges shall be clearly displayed (Example 5 and Example 8, column "Measuring range").

Example 5:

<table>
<tr><td colspan="6">Калибрациска и мерна можност (Calibration and Measurement Capability) - CMC</td></tr>
<tr><td colspan="6">Електрични големини / Еднонасочен нискофреквентен напон
Electricity / DC/LF Voltage</td></tr>
<tr><td colspan="6">Локација каде се изведува калибрацијата:</td></tr>
<tr><td>Реден број
No.</td><td>Предмет на калибрација
Subject of calibration</td><td>Мерен опсег
Measuring range</td><td>Мерна неодреденост
Measurement uncertainty*</td><td>Метода на калибрација
Method of calibration</td><td>Забелешка
Remark</td></tr>
<tr><td>1</td><td rowspan="5">Дигитални мултиметри, волтметри и мерила на наизменичен напон кои не се наменети за оваа величина како дел од некоја друга и се со фреквенција помала од 1 MHz
Digital multimeters, voltmeters and measuring instruments of AC Voltage which are not primary untended for measuring quantities of a different type and with frequency lower than 1 MHz</td><td>100 mV÷1 V
(40 Hz ÷100 kHz)</td><td>0,5 mV/V</td><td rowspan="5">EURAMET/cg.15/V.2 "Guidelines on the Calibration of Digital Multimeters"</td><td rowspan="5">Дирекна метода на калибрација со калибратор WAVETEK 4808

Спредбена метода на калибрација со мултиметар AGILENT 3458A</td></tr>
<tr><td>2</td><td>1 V ÷ 10 V
(40 Hz ÷100 kHz)</td><td>2 mV/V</td></tr>
<tr><td>3</td><td>1 V ÷ 10 V
(100 kHz ÷1 MHz)</td><td>12 mV/V</td></tr>
<tr><td>4</td><td>10 V ÷ 100 V
(40 Hz ÷100 kHz)</td><td>3 mV/V</td></tr>
<tr><td>5</td><td>100 V ÷ 1000 V
(40 Hz ÷20 kHz)</td><td>1,4 mV/V</td></tr>
</table>

5. Decimal numbers are written with a comma ",".
6. All measurement units shall be expressed in SI units, and if they are not, they shall be converted and expressed in SI units if possible. In cases where this is not possible, the justification for such expression shall be supported by reference documents where units of non-SI system are given.

Column 4 "Measurement Uncertainty*": This column lists the expanded measurement uncertainty with a coverage factor *k* (in the case of a normal Gaussian distribution, *k* is a value of 2), which refers to:

1. Calibration of measuring instruments, given in column 2 of the table with the measuring range given in column 3;
2. Method of calibration, in accordance with the reference documents listed in column 5 and with the equipment specified in the controlled laboratory documentation or in column 6;
3. The working environment in which the calibration is performed, and is specified in the controlled laboratory documentation;
4. Execution of activities (preparation, overall measurement process, evaluation, etc.) by the selected technical staff in accordance with the conditions prescribed in the calibration methods or other regulations.

If there are conditions that have a great impact on the measurement uncertainty (most often it refers to the type ofmeasuring instrument, its accuracy, accuracy class, etc.), it is recommended to list them in the form of a note in column 2, if they refer to the characteristics of the measuring instrument (given in Example 5) or in column 6, if these influences do not come from the measuring instrument r (eg, from the standards used or from other sources, as in Example 9).

When witnessing the method, during the accreditation, the laboratory shall show all relevant accompanying and auxiliary elements (materials, equipment, etc.) with which the measurement uncertainty is expressed, as well as the calculation / evaluation methodology, estimates, additional factors and analyzes, which affect the calculation.

The measurement uncertainty, which is listed in column 4, must not be a value that the laboratory can achieve in special conditions and circumstances, such as: longer measurement period, certain personnel, specific ambient conditions and the like. All these conditions and circumstances do not occur in normal practice and are not specified in the laboratory documentation as such.

If the condition for normal distribution is not met, a coverage factor k is used, which corresponds to a probability interval of approximately 95%. In case of using the coverage factor, which corresponds to another coverage interval, it is stated in addition to the declared measurement uncertainty.

*A note below the range provides an explanation of the measurement uncertainty arising from the following: The measurement uncertainty is expressed by the expanded measurement uncertainty in a given field EA-4/02. The measurement uncertainty is expressed as an expanded measurement uncertainty with the coverage factor k=2, which when using the Gaussian distribution gives a confidence interval of approximately 95%. (In the case of a different probability distribution, the value of k is also different from k=2, however in this case the expanded uncertainty should give a confidence interval of approximately 95%).

Rules for calculation and expression of measurement uncertainty by calibration laboratories:

1. Calibration laboratory shall calculate and express the measurement uncertainty in compliance with the GUM.
2. The measurement result shall include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates the measurement result should be reported as $y \pm U$ associated with the units of y and U. Tabular presentation of the measurement result may be used and the relative expanded uncertainty $U / |y|$ may also be provided if appropriate. The coverage factor and the coverage probability shall be stated

on the calibration certificate. To this an explanatory note shall be added, which may have the following content:
"The reported expanded measurement uncertainty is stated as the standard measurement uncertainty multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %."

3. Uncertainty is given in absolute value for the measuring point and it is rounded to two significant digits. Column 4 indicates only the value and the SI unit of measure without indicating "±".
4. It is not allowed to present the measurement uncertainty as an open interval, ie $U > 12\%$ relative.
5. If for certain measuring instruments it is usual to use the expression of measurement uncertainty in relative value, it is necessary to indicate that it is relative, only if it is expressed in percentage. Other estimates are not allowed such as ppm, pph and the like.
   Example 6: 0,1% relative or only 0,001
   12 ppm – may not be used, but must be written as $12 \cdot 10^{-6}$
6. In certain cases, when the measurement uncertainty is expressed depending on a parameter, such as: measured value, measuring range or a constant, it is necessary for this parameter, in column 6, to be stated and defined.
   Example 7: If the measurement uncertainty is $34\ \mu m + 14 \cdot 10^{-6} \cdot L$ then in column 6 write "L is the measured length". The table is shown in Example 7.
   Example 8: The measurement uncertainty for calibration of analog manometers if it is expressed as $0{,}65\ \mu bar + 4{,}4 \cdot 10^{-5} \cdot p_e$ in column 6 states "p_e - deviation of the sample before the calibration cycle". The table is shown in Example 9.
7. If the measurement uncertainty refers to the calibration of meters with precisely defined technical characteristics, it is necessary to declare them.
8. The numerical values of the expanded uncertainty (according to Global ACI-TECH-1-009, 5.3), shall be given with at most two significant digits.

Note: Asymmetric uncertainty may require a non - $y \pm U$ - shaped representation. This also refers to uncertainties determined by Monte Carlo simulations (distribution propagations) or logarithmic units.

Example 8: Calibration of water meters for hot and cold water *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Калибрациска и мерна можност (Calibration and Measurement Capability) - CMC					
Механички големини / Волумен и проток на флуиди *Mechanical quantities / Volume and flow of fluids*					
Локација каде се изведува калибрацијата:					
Реден број No.	Предмет на калибрација *Subject of calibration*	Мерен опсег *Measuring range*	*Measurement uncertainty**	Метода на калибрација *Method of calibration*	Забелешка *Remark*
1	Калибрација на водомери за топла и ладна вода *Calibration of water meters for hot and cold water*	0,2 $m^3/h \div 40\ m^3/h$	При Q_n е 0,2% relative	STN 12345 (IP-20)	Масен метод со фиксен проток и користен медиум е ладна вода Q_n– номинален проток Q_{min} – максимален проток

			При Q_{min} е 0,39 % relative		*Mass method with fixed flow and cold water as medium used* Q_n – *nominal flow* Q_{min} – *maximum flow*

Note: In order to avoid ambiguities in the expression of the values of the calibration measurement capability CMC, the requirements of Global ACI-TECH-1-009 (item 4 and item 5) and the guideline for expressing measurement uncertainty: JCGM GUM, must be applied.

Column 5 "Calibration method": This column lists the reference documents with which the laboratory performs the calibration or its internal procedures (in the case of laboratory developed methods which are validated. Reference document means: standards, relevant publications from the metrological organizations EURAMET and OIML as well as from National Metrological Institutes, which are members of these metrological organizations, published papers in the field, instructions from manufacturers that are validated and have their own version and year of issue. The laboratory shall clearly state the calibration method, whether a reference document or an internal procedure is used, and it is not allowed to specify both documents.

Column 6 "Note": This column lists important specifications which, by their nature, are not covered by the previous columns, but are restrictive:

1. List all factors that are characteristic in terms of measurement uncertainty, as well as all additional clarifications, in terms of the calibration method used by the laboratory.

Example 9: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

<table>
<tr><td colspan="6">Калибрациска и мерна можност (Calibration and Measurement Capability) – CMC</td></tr>
<tr><td colspan="6">Механички големини / Маса
Mechanical quantities / Mass</td></tr>
<tr><td colspan="6">Локација каде се изведува калибрацијата:</td></tr>
<tr><td>Реден број
No.</td><td>Предмет на калибрација
Subject of calibration</td><td>Мерен опсег
Measuring range</td><td>Мерна неодреденост
Measurement uncertainty*</td><td>Метода на калибрација
Method of calibration</td><td>Забелешка
Remark</td></tr>
<tr><td>1</td><td rowspan="4">Неавтоматски ваги
Non-automatic weighing instruments</td><td>1 g ÷ 10 g</td><td>18 μg ÷ 35 μg</td><td rowspan="4">EURAMET/cg.18/V.4“Guidelines on the Calibration of Non-Automatic Weighing Instruments”</td><td rowspan="4">Uncertainties quoted depend on the performance of the weighing instruments under calibration, and can not be less than the uncertainty of the weights used for the calibration.</td></tr>
<tr><td>2</td><td>10 g ÷ 100 g</td><td>35 μg ÷ 92 μg</td></tr>
<tr><td>3</td><td>0,1 kg ÷ 1 kg</td><td>92 μg ÷920 μg</td></tr>
<tr><td>4</td><td>1 kg ÷ 10 kg</td><td>0,92 mg ÷ 9,2 mg</td></tr>
<tr><td colspan="6">Механички големини / Притисок и вакуум</td></tr>
</table>

Mechanical quantities / Pressure and vacuum					
5	Позитивен и негативен притисок p_e Positive and negative pressure p_e	-1 bar ÷ -0,03 bar	5,0 µbar +5,0 x $10^{-5}p_e$	DIN EN 837:1997 DKD-R 6-1:2014 EURAMET cg-3, Version 1.0 EURAMET cg-17, Version 2.0	Медиумот за задавање на притисок е гас p_e– отстапување на примерокот пред циклусот на калибрација (во мерна единица како во мерниот опсег) Pressure medium is gas p_e - deviation of the sample before the calibration cycle (in measurement unit as in the measuring range)
6		-0,03 bar ÷ 0,15 bar	0,25 µbar +3,3 x $10^{-5}p_e$		
7		0,15 bar ÷ 1,8 bar	3,4 µbar +1,9 x $10^{-5}p_e$		
8		1,8 bar ÷ 7 bar	14 µbar +1,9 x $10^{-5}p_e$		
9		7 bar ÷70 bar	0,4mbar +2,6 x $10^{-5}p_e$		

2. Certain measuring instruments that have a specific nature and are protected as a brand by the manufacturer with a password such asdevices measuring the breaking force of vehicles, emission testers for diesel powered motor vehicles, meters for exhaust emission quality of gasoline powered motor vehicles - gas analyzers, etc.
3. Measuring instruments with specific and non-standard dimensions of reference templates to be calibrated such as: system - chamber for measuring emission testers for diesel powered motor vehicles.

Example 10: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Калибрациска и мерна можност (Calibration and Measurement Capability) – CMC					
Оптички големини / *Optical quantities* Особини на оптички системи / *Optical system properties*					
Локација каде се изведува калибрацијата: *Location where calibration is performed*:					
Реден број No.	Предмет на калибрација *Subject of calibration*	Мерен опсег Measuring range	Мерна неодреденост *Measurement uncertainty**	Метода на калибрација *Method of calibration*	Забелешка Remark
1	Уреди за мерење на затемнетоста на издувните гасови од возилата опремни со дизел мотори – Опациметри / *Emission testers for diesel*	0 % ÷ 100 %	0,26 %		Референтни еталони за: / Reference standard for: CARTEC – LCS 2100 CARTEC – LCS 2400 MAHA - MDO 2 CAPELEC/SUN
2		0 m^{-1} ÷ 99,99 m^{-1}	0,0059 m^{-1}		

	powered motor vehicles				– DSS 3 …..

4. The scope of application of calibration activities, e.g. in cases where there are technical limitations or when it comes to a regulated sector where reference is made to relevant laws or directives, etc.

6. GUIDELINES FOR CERTIFICATION BODIES FOR PRODUCTS, PROCESSES AND SERVICES

The scope of activities of the certification bodies for products, processes and services that require accreditation is stated in the Application for Accreditation of Certification Bodies for Products, Processes and Services OB 05-04-1. By filling in the relevant tables, the applicant shall indicate the scope for which they are seeking accreditation and which will be, after granting accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the Accreditation Certificate OB 05-36-1.

Sample table showing the scope of the certification body for products, processes and services:

Бр. *No.* (1)	**Производи/процеси/услуги** *Products/Processes/Services* (2)	Сертификациона шема *Certification Scheme* (3)	Стандард(и) и/или други нормативни документи *Standard(s) and/or other normativ documents* (4)

Column (1)
In the **first column** of the table are the ordinal numbers of the products / processes / services for which certification has been granted.

Column (2)
The **second column** of the table lists the products / processes / services for which certification has been granted.

Column (3)
The **third column** of the table lists the applied certification scheme*.

Under the scheme name, the conformity assessment methods as set out in Table 1 of MKS EN ISO / IEC 17067: 2013 must be listed. The applicable activities of Part II and, if applicable, Part VI of Table 1 ISO / IEC 17067 (for example, type testing or annual support system audits) must be mentioned.

Part II and VI of MKS EN ISO / IEC 17067:2013

II Determining the characteristics, if applicable, through:
a) (type) testing
b) inspection

c) design evaluation
d) evaluation of services or processes
e) other determining activities, e.g. verification

VI Supervision, if applicable, through:
a) testing or inspection of market samples
b) testing or verification of factory samples
c) evaluation of production, service delivery or process operation
d) management system audits in combination with random tests or inspections

* **Certification scheme** is a certification system related to specific products to which the same specific requirements, rules and procedures apply.

A **scheme owner** is a person or organization responsible for developing and maintaining a specific certification scheme.
Note: The scheme can be owned by the certification body itself, a group of certification bodies, a government body, manufacturers and their associations, trade associations that buy or sell products subject to certification, NGOs and consumer organizations, standardization bodies.
Accreditation bodies cannot be owners of a scheme.

Column (4)
The **fourth column** lists the standard(s) and/or other normative documents, including their date of publication, on the basis of which it is assessed whether the product(s), process(s) or service(s) is harmonized with them.

Examples of certification of construction products in a non-harmonized field: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Бр. *No.* (1)	**Производи/процеси/услуги** *Products/Processes/Services* (2)	**Сертификациона шема** *Certification Scheme* (3)	**Стандард(и)** *Standard(s)* (4)
1.	Бетон/ Concrete	2+	МКС EN 206:2013+A2:2022 Бетон - Спецификации, својства, производство и сообразност *Concrete - Specification, performance, production and conformity* МКС 1016:2018+A1:2020 Бетон - Спецификација, својства, производство и сообразност - Правила за употреба на МКС EN 206:2014+A1:2017

Examples of certification of construction products in a harmonized field: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards)*

Бр. *No.* (1)	Производи/процеси/услуги *Products/Processes/Services* (2)	Систем на ОППС *AVCP system* (3)	Стандард(и) *Standard(s)* (4)
1.	Цемент/ Cement	1+	МКС EN 197-1:2012, Цемент - Дел 1: Состав, спецификации и критериуми за сообразност за обичен цемент *Cement - Part 1: Composition, specifications and conformity criteria for common cements*
2.	Агрегати/Aggregates	2+	МКС EN 12620+A1:2009, Агрегати за бетон *Aggregates for concrete* МКС EN 13043:2006, МКС EN 13043:2006/AC:2006, Агрегат за битуменски мешавини и површински обработки за патишта, аеродроми и други сообраќајни површини, *Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas* МКС EN 13055-1:2016 Лесни агрегати - *Lightweight aggregates* МКС EN 13139:2006, МКС EN 13139:2006/AC:2006, Малтерни маси *Aggregates for mortar* МКС EN 13383-1:2006, МКС EN 13383-1:2006/AC:2006, Делкан камен - Дел 1: Спецификација *Armourstone - Part 1: Specification* МКС EN 13450:2006, МКС EN 13450:2006/AC:2006, Агрегати за железнички товар *Aggregates for railway ballast*

ОППС - систем или системи за оцена и потврда на постојаност на својствата на секој вид или категорија на градежни производи/ *(AVCP) the system or systems of assessment and verification of constancy of performance of the construction product (AVCP)*

Examples of certification of production processes of organic agricultural products, in accordance with the Law on Organic Agricultural Production *(These are just examples of writing the scope and may not conform to the current version of the methods/standards/regulations)*

Бр. *No.* (1)	**Производи/процеси/услуги** *Products/Processes/Services* *(2)*	Сертификациона шема, Стандард(и) и/или други нормативни документи Certification Scheme, Standard(s) and/or other normativ documents *)* (3) + (4)
1.	Растенија и растителни производи, вклучувајќи и самоникнати видови Сточарско органско производство, вклучувајќи пчеларство и пчеларски производи Производство и преработка, на прехранбени производи што се состојат од растителни и сточни производи, вклучувајќи и трговија на органски земјоделски производи *Plant and plant products, including wild collection* *Livestock and livestock products, including beekeeping and beekeeping products* *Production and processing of plant and livestock products and foodstuffs composed of plant and livestock products, including trade of organic agricultural products*	Закон за органско земјоделско производство на РМ („Сл.Весник на РМ бр.146/2009“ и „Сл.Весник на РМ бр.53/2011“) Правилник за начин и постапка за вршење стручна контрола во органско земјоделско производство („Сл.Весник на РМ бр.163/2010“), Правилник за формата и содржината на формата на потврдата, начинот на нејзиното издавање, како и постапката за собирање, пакување, превоз и складирање на органски производи („Сл.Весник на РМ бр.163/2010“), Правилник за правила и постапки во растително органско производство („Сл.Весник на РМ бр.163/2010“), Правилник за правила и постапки во пчеларството („Сл.Весник на РМ бр.163/2010“), Правилник за постапките на одгледување, минимум површини за сместување на различни видови животни и максимален број на животни по хектар („Сл.Весник на РМ бр.162/2010) *Law on Organic Agricultural Production (Official Gazette no 146/2009) and the Law amending the Law on Organic Agricultural Production (Official Gazette No.53/2011),* *Regulation on the Manner and procedure for performing of Professional control of the organic Agricultural Production (Official Gazette No.163/2010),* *Regulation on the form and content of the certificate the manner of its issuance and the procedure for collecting packaging, transport and storage of organic products (Official Gazette No.163/2010), Regulation on rules and procedures in organic crop production (Official Gazette No.163/2010),* *Regulation on rules and Procedures in beekeeping (Official Gazette No.163/2010),* *Regulation on the procedures for cultivation the minimum area to accommodate a variety of species and maximum number of animals per hectare (Official Gazette No.162/2010)*

7. GUIDELINES FOR CERTIFICATION BODIES FOR MANAGEMENT SYSTEMS

The scope of activities of the certification bodies for management systems that require accreditation is stated in the Application for Accreditation of Certification Bodies for management systems OB 05-03-1. By filling the application the applicants shall indicate the management system standard and the activities for which they are seeking accreditation and

which will be, after granting accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the Accreditation Certificate OB 05-23.

Example:
Quality management system certification, according to МКС EN ISO 9001:2015, by applying МКС EN ISO/IEC 17021-3:2019

IAF*	Подрачје	NACE rev.2**
8	Издавачка дејност/*Publishing companies*	58.1
9	Печатарска дејност/*Printing companies*	18
28	Градежништво/ *Construction*	41, 42
29	Трговија на големо и трговија на мало; Поправка на моторни возила, мотоцикли и предмети за лична употреба и за домаќинствата/ *Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods*	45, 46, 47

**IAF code as per IAF ID 1:2023*
***NACE code, as per Regulation 1893/2006/EC of the European Parliament and of the Council*

8. GUIDELINES FOR INSPECTION BODIES

The scope of activities of inspection bodies seeking accreditation is stated in the Application for Accreditation of Inspection Bodies OB 05-06-1. By filling in the relevant tables, the applicant shall indicate the scope for which they are seeking accreditation and which will be, after granting accreditation, re-accreditation, extension of accreditation or after the changes made, specified in the Annex to the Accreditation Certificate OB 05-31-1.

Sample table showing the scope of an inspection body:

Бр.	**Подрачје на инспекција производ, процес, инсталација** *Field of inspection product, process, installation*	**Тип на инспекцијата (прва, периодична вонредна и.т.н)** *Inspection type (first, periodical, extraordinary etc.)*	**Инспекциски методи** *Inspection methods*	**Легислатива на која се реферираат методите** *Legislation which refers to the methods*

Column (1)
In the **first column** of the table are the ordinal numbers of the product / process that is part of the accredited activity.

Column (2)
The **second column** of the table lists the field of product inspection, process, installation.

Column (3)

The **third column** of the table indicates the type of inspection (first, periodic, extraordinary, before commissioning, at the request of the customer, conformity assessment of a new product which lists the modules according to which the conformity assessment is performed, etc.)

Column (4)
The **fourth column** lists the inspection methods and procedures according to which the inspection bodies perform inspections. If the inspection method is performed in full compliance with the standard, then the standard (with the year of issue of the standard) can be stated as a replacement for the internal inspection method.

Column (5)
The **fifth column** states the legislation (if applicable) according to which the inspection is performed, as well as bylaws and other regulations. Also clearly and unequivocally, if necessary, the exclusion or specification of the application of certain articles or parts of articles of the legislation should be stated.

Examples of inspection in a regulated field: *(These are just examples of writing the scope and may not conform to the current version of the methods/standards/regulations)*

Бр.	**Подрачје на инспекција производ, процес, инсталација** *Field of inspection product, process, installation*	**Тип на инспекцијата (прва, периодична вонредна и.т.н)** *Inspection type (first, periodical, extraordinary etc.)*	**Инспекциски методи** *Inspection methods*	**Легислатива на која се реферираат методите** *Legislation which refers to the methods*
1.	Лифтови	Оцена на сообразност - Поединечна верификација на лифтови (модул “G”) - Испитување на тип на лифтови (модул “B”) - Завршна инспекција на лифтови	Процедура за оцена на сообразност на лифтови Работно упатство за испитување и проверка на лифтови при оцена на сообразност	Правилник за пуштање на пазар на лифтови и сигурносни уреди за лифтови (Сл. весник на Р.М. бр. 23/2007
	Lifts	*Conformity assessment* *- Unit verification of*	*Procedure for conformity assessment of lifts;*	*Rulebook for placement on the market of lifts and lift safety components (Official Gazette of R.M. No. 23/2007)*

		lifts (Module G) - Type examination of lifts (Module B) - Final inspection of lifts	*Instructions for testing and examination of lifts during conformity assessment*	
2.	- мостовски дигалки (кранови) - портални и полупортални дигалки (кранови) - подвижни и неподвижни конзолни дигалки (кранови) - подвижни и неподвижни дигалки (кранови) со столб или кула - мобилни дигалки (кранови) - дигалки монтирани на возила	- Технички преглед и испитувања пред ставање во употреба (прв технички преглед) - Периодичен и вонреден технички преглед и испитувања	Процедура за технички преглед на дигалки и индустриски транспортери Работно упатство за испитување и проверка на дигалки и индустриски транспортер	Правилник за користење на дигалки и индустриски транспортери (Сл. весник на Р.М. 32/2009)
	- bridge cranes *- gantry and semi-gantry cranes* *- movable and stationary jib and cantilever cranes* *- movable and stationary mast and tower cranes* *- mobile cranes* *- hoists mounted on vehicles (loader cranes),*	*- Technical examination and tests of lifts before putting into service (first – initial technical examination)* *- Periodical and extraordinary technical examination and tests*	*Procedure for technical examination of cranes and industrial conveyors* *Instructions for testing of cranes and industrial conveyors during technical examination;*	*Rulebook on use of hoists and industrial conveyors (Off. Gazette of R.M. 32/2009);*