
 <p>AKREDITACIONO TIJELO Crne Gore</p>	<p>AKREDITACIONO TIJELO CRNE GORE ACCREDITATION BODY OF MONTENEGRO</p>	<p>Reference/Date: PR.11-1/18.04.2022.</p>
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PROCEDURE FOR EXPRESSION OF SCOPES OF ACCREDITATION

	Name and surname	Function	Date	Signature
Reviewed by:	Tanja Radovic	Head of the Accreditation Service/QMR	18.04.2022.	
Approved by:	Anita Krulanović	Director	18.04.2022.	
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1. SUBJECT MATTER AND SCOPE

This document shall be applied for the purposes of formulating, determining and expressing the scope of accreditation of a conformity assessment body.

The document is applied by:

- assessors of the Accreditation Body of Montenegro when verifying the competence of the conformity assessment body for the requested (sought) scope of accreditation,
- Accreditation Body of Montenegro when determining and expressing the scope of accreditation of conformity assessment bodies.

This document shall not be applied for the purposes of determining and expressing the flexible scope of accreditation, which is the subject of a separate document (procedure PR.12 - Flexible scope of accreditation).

2. ABBREVIATIONS AND DEFINITIONS

2.1 ABBREVIATIONS

ATCG - Accreditation body of Montenegro

CAB - conformity assessment body

2.2 DEFINITIONS

accreditation - third-party (accreditation body) attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

conformity assessment body - body that performs conformity assessment activities and that can be the object of accreditation

conformity assessment activity - activity conducted by a conformity assessment body when assessing conformity

granting accreditation - awarding accreditation for a defined scope of accreditation

scope of accreditation - specific conformity assessment activities for which accreditation is sought or has been granted

accreditation scheme - rules and processes related to the accreditation of conformity assessment bodies to which the same requirements apply

Note: Accreditation scheme requirements include, but are not limited to ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065

For the purposes of this document, other relevant definitions from standards EN ISO/IEC 17011, EN ISO/IEC 17025, EN ISO 15189, EN ISO/IEC 17020, EN ISO/IEC 17021-1, EN ISO/IEC 17065, EN ISO 19011 and EN ISO/IEC 17000 are used.


3. RELATIONSHIP WITH OTHER DOCUMENTS

MEST EN ISO/IEC 17011:2018, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies

MEST EN ISO/IEC 17025:2018, General requirements for the competence of testing and calibration laboratories

MEST EN ISO 15189:2023, Medical laboratories - Requirements for quality and competence;

MEST EN ISO/IEC 17020:2013, Conformity assessment - Requirements for the operation of various types of bodies performing inspection

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MEST EN ISO/IEC 17065:2020, Conformity assessment - Requirements for bodies certifying products, processes and services

MEST EN ISO/IEC 17021-1:2018, Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements

ILAC-G18:12/2024, Guideline for describing Scopes of Accreditation

EA-4/02 M: 2022, Evaluation of the Uncertainty of Measurement in Calibration

MEST ISO 22003-1:2022, Food safety –Part 1: Requirements for bodies providing audit and certification of food safety management systems

EA 3/12 M: 2013, EA Policy of accreditation of organic production certification

EA 3/12 M: 2022, EA Policy of accreditation of organic production certification

EA-4/17 M: 2022, EA position paper on the description of scopes of accreditation of medical laboratories

ILAC-G28:07/2018, Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies

IAF ID 1:2020, IAF Informative Document for QMS and EMS Scopes of Accreditation

IAFMD 22:2019, Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)

PA.01 - Rules of Accreditation

PR.01-5 – Assessment of conformity assessment bodies

ZPR.01.34-1 - Addendum to the accreditation certificate for testing laboratories

ZPR.01.35-1 - Addendum to the accreditation certificate for calibration laboratories

ZPR.01.39-1 - Addendum to the accreditation certificate for medical laboratories

4. DESCRIPTION OF TASKS AND RESPONSIBILITIES

4.1 GENERAL PRINCIPLES

In accordance with the accreditation rules (*PA.01 – Rules of Accreditation*) and the procedure for assessment (*PR.01- Assessment of conformity assessment bodies*), the CAB submits to ATCG the requested scope of accreditation as a part of the Application for accreditation.

During the accreditation process, ATCG verifies the competence of the CAB for the requested scope of accreditation.

Upon completion of the accreditation process, i.e. after determining CAB's competence, ATCG grants to the CAB the accreditation with a clearly defined scope of accreditation, i.e. specific conformity assessment activities for which CAB demonstrated its competence during the implementation of the accreditation procedure.


Note: The granted scope of accreditation may differ from the requested scope of accreditation.

At any time during the validity of the accreditation, the CAB can apply for a change of the granted scope of accreditation (extending or reducing the granted scope of accreditation), in accordance with the accreditation rules (*PA.01 – Rules of Accreditation*).

ATCG defines and expresses the scope of CAB's accreditation in the form of abbreviated and detailed scope of accreditation.

The abbreviated scope of accreditation is stated descriptively (textually) on the first page of the Addendum to the accreditation certificate for each CAB, while the detailed scope of accreditation is presented tabularly within the Addendum.

Accreditation certificate addendums, which contain CABs' abbreviated and detailed scopes of accreditation, are publicly available on the ATCG web portal (www.akreditacija.me).

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4.2 EXPRESSION OF THE SCOPE OF ACCREDITATION OF TESTING LABORATORIES

4.2.1 General

Abbreviated and detailed scope of accreditation of testing laboratories is specified in the relevant Addendum to the accreditation certificate (form ZPR.01.34-1 - Addendum to the accreditation certificate for testing laboratories).

4.2.2 Classification of fields and items of testing

For the purpose of expressing the scope of accreditation of testing laboratories, the ATCG established the following classification of fields and items of testing:


a) fields of testing, with sub-fields (or techniques) of testing

Ord. No.	Field of testing	Sub-fields (or techniques) of testing
1.	Acoustic and noise tests	Noise tests in the living and working environment
		Noise sources
		Building acoustics
2.	Biological, biochemical tests	Biochemical, immunochemical tests
		Biological tests (pollen, phytoplankton, nematodes, etc.)
		Genetic tests
3.	Chemical (analytical) tests	Chromatography (GC, HPLC, LC/MS, TLC)
		Atomic spectrophotometry (AAS, ICP, ICP/OES, ICP/MS); UV/VIS spectrophotometry
		Classic methods (volumetric, gravimetric, pycnometric, potentiometric, distillation, etc.)
		Physical-chemical methods (refractometry, conductometry, polarimetry, colorimetry, turbidimetry, etc.)
		IR/MS
		IR/FTIR, XRF, WDXRF
		NMR
4.	Clinical tests in the field of medicine and veterinary medicine	Hematology
		Clinical biochemistry
		Anatomical pathology (cytopathology and histopathology)
		Immunochemistry
		Immunoematology
		Human Genetics (Molecular)
		Imaging tests
Physiological tests		
5.	Electrical and electronic tests	Testing of electrical permittivity and dielectric strength, resistance/impedance
		Testing of the IP/IK code
		Testing of lighting intensity
		Other electrical and electronic testing
6.	Electromagnetic Compatibility (EMC)	
7.	Meteorological measurements	



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8.	Fire tests	
9.	Forensic tests	Molecular genetics (e.g. DNA profile, paternity)
		Toxicological tests (presence of medicines, poisons and drugs)
		Analysis of evidence traces
		Forensic testing in accordance with the WADA sector scheme
		Dactyloscopy analysis (fingerprint)
		Forensic ballistics
		Chemical tests
10.	Mechanical, metallographic tests	Mechanical tests
		Metallographic tests (macroscopic, light and electron microscopic metallography)
11.	Microbiological tests	Classic microbiological tests
		Immuno-serological tests
		Molecular genetics (PCR)
		Resistance/sensitivity of bacteria to antibiotics/chemotherapeutics
12.	Non-destructive testing	Radiographic testing
		Visual examination
		Testing with magnetic particles
		Penetrant testing
		Ultrasound testing
		Eddy current testing
		Testing of electrical permittivity of insulation
13.	Physical tests	Measurements of temperature, flow, humidity, pressure, density
		Test of strength and impermeability, functionality, characteristics, visual inspection, permeability
		Measurements of microclimatic parameters of the working environment
		Examination in the field of thermos technics, including thermographic and thermovision examinations
		Vibrations that potentially affect the human body
		Vibrations (machines, rolling bearings, vehicles, etc.)
14.	Ionizing radiation	Sources of ionizing radiation
		Tests of devices emitting ionizing radiation
		Gamma spectrometry
		Dosimetry
		Alpha, beta activity
		Neutron measurements
		Radionuclide concentration
15.	Non-ionizing radiation	Electromagnetic fields
		IR-radiation
		UV radiation

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16.	Sensory tests	
17.	Sampling	Emission, immission
		Asbestos, fibres, dust and particles
		Chemical products, including fertilizers
		Construction products
		Detergents, disinfectants, antimicrobials and soaps
		Food and feed, including beverages
		Gases
		Coal, oil and oil derivatives
		Plant material including seeds and grains
		Soil, mud, sediment
		Animal material, tissues and fluids
		Human material, tissues and fluids
		Waste, pollutants and effluents
		Water
Ionizing radiation		
18.	Other tests*	

*When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, also specify some other fields/sub-fields of testing that are not covered by the above classification

b) items of testing, with subtypes of items of testing:

Ord. No.	Item of testing	Subtypes of items of testing
1.	Agricultural products, including animal feed	Agricultural products
		Seeds of agricultural plants (planting material)
		Animal feed
2.	Asbestos (including asbestos removal)	
3.	Biological material for testing	Biological material of human origin
		Biological material of animal origin
		Plant matter
4.	Chemicals, chemical products, cosmetics (including fertilizers and paints)	Cosmetics
		Means for maintaining hygiene
		Means for maintaining cleanliness in the household
		Chemicals and chemical preparations
		Fertilizers
		Colors
		Pesticides and pesticide formulations
		Coolants, antifreeze and brake fluids
5.	Construction products, materials and structures	Stone and stone aggregate
		Flat, profiled glass products and blocks



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		Concrete and products, chemical additives to concrete
		Asphalt and hydrocarbon binders, bitumen
		Floor coverings, ceramics
		Refractory materials
		Inorganic materials
		Heating devices
		Chimney
		Metal construction products and auxiliary equipment
		Soil, geotextile and geomembranes
		Reinforcing steel (concrete steel)
		Cement
6.	Electrical products and equipment	Low voltage equipment and installations
		Lightning protection installations
		Equipment and installations of high and medium voltage
		Transformers and other energy equipment
		Ex devices and equipment
		Electromedical devices and equipment
7.	Telecommunications and electronics, including software	
8.	Industrial materials and products, including metals and composites	Metal materials
		Metallic and non-metallic raw materials
		Ores, alloys, metals and composites
		Welded joints, protection of materials, coatings, AKZ
		Metal waste
		Forgings/Castings
		Iron and steel
9.	Environmental samples (air, water, soil, waste)	Ambient air, working environment
		Water, drinking water
		Soil
		Waste
		Waste gas, landfill gas
		Clean rooms
		Asbestos in the air
10.	Fuels (gas, liquid and solid) and lubricants	Liquid fuels of petroleum origin (petroleum derivatives and LPG)
		Natural gas
		Lubricants, industrial oils and related liquids



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		Solid fuels
		Mineral insulating oils for use in transformers and electrical devices and insulating paper
		Gases and gas mixtures
11.	Furniture	
12.	Glass, ceramics	
13.	Machines, plants, equipment	Machines (household appliances, industrial machines)
		Electric power plants
		Nuclear plants
		Gas devices and installations
		Equipment under pressure
		Construction structures
		Industrial fittings
		Automatic fan burners for gaseous fuels - combustion products
		Hydraulics, pneumatics
		Rolling bearings
		Thermal turbomachines
14.	Medical devices and equipment	Medical equipment and materials
		Medical devices
15.	Military equipment, including explosives and ballistics	Military equipment, including explosives
		Ballistics
16.	Optical equipment	
17.	Material in contact with food, skin and mucous membranes (excluding personal hygiene products)	Accessories and packaging for food
		Material in contact with food
		Material in contact with skin and mucous membranes (eg. jewellery)
18.	Personal protective equipment	Protective clothing
		Protective footwear
		Other protective equipment
19.	Pharmaceutical products	Pharmaceutical preparations
		Medicines
20.	Plastic and rubber products	Plastics and products made from plastics
		Rubber products
		Insulation products and materials
21.	Products for human consumption,	Products of plant origin

	including food	Products of animal origin
		Juices and soft drinks
		Wine
		Alcoholic beverages
22.	Textiles, leather, fabric, yarn, clothing	Textiles and textile products, including clothing
		Leather and leather products
		Fabric
		Yarn
		Footwear
23.	Tobacco products	Tobacco
		Tobacco products
24.	Toys, sport and hobby equipment	
25.	Vehicles	Railway vehicles
		Vehicles
26.	Wood	
27.	Packaging and packaging material	
28.	Other items of testing*	

**When defining the requested (desired) scope of accreditation, the applicant for accreditation may, where applicable, also specify some other items of testing that are not covered by the above classification*

4.2.3 Expression of the abbreviated scope of accreditation

The abbreviated scope of accreditation of testing laboratories is expressed descriptively (textually) by stating the field of testing in relation to the item(s) of testing (e.g. chemical testing of food products, animal feed and tobacco products).


4.2.4 Expression of the detailed scope of accreditation

The detailed scope of accreditation of testing laboratories is expressed tabularly in the manner shown in Table 1, with an indication of whether the test in question is performed in the laboratory or in the field.

Note: When defining the elements of the detailed scope of accreditation, the guidelines from document ILAC-G18:12/2021 were used

Ord. No.	Item of testing (material/product)	Field of testing	Type of testing and/or characteristic to be measured (testing technique)	Measurement range (where applicable)	Reference document	Location label

Table 1. Elements of the detailed scope of accreditation of testing laboratories

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The elements for expression of the detailed scope of accreditation shall be as follows:

- **Item of testing, i.e. material/product** - in this column, the item of testing is stated, whereby it is necessary to take into account the classification specified in clause 4.2.2 of this document (e.g. Personal protective equipment/Protective clothing; Pharmaceutical products/Medicines, etc.), or where appropriate the specific material/product that is the item of testing (e.g. Protective boots, Diesel fuel; Milk; Textiles, etc.);
- **Field of testing** – in this column, the relevant field/sub-field of testing is stated, whereby it is necessary to take into account the classification specified in clause 4.2.2 of this document (e.g. Mechanical tests; Microbiological tests/Immuno-serological tests, etc.);
- **Type of testing and/or characteristic to be measured (testing technique)**, in this column the type of testing and/or the characteristic which is measured is stated, as well as the testing technique where applicable (e.g.: Shore hardness determination; Ultrasonic thickness test; Iron content determination (ICP-OES), etc.);
- **Measurement range** - where applicable, the measurement range is stated in this column (e.g. 0.1 % - 7.0 %);
- **Reference document** - this column contains references to relevant test methods, whereby they can be:
 - **standard methods** - methods developed by standardization organizations or other recognized organizations whose methods are generally accepted in a particular technical field. For standard methods, the valid edition of the standard is specified, indicated by the reference and the year of publication, and when appropriate, the part of the standard in which the test procedure is described (clauses of the standard) is additionally specified.
Note: The laboratory shall ensure the use of the latest valid edition of the standard, unless it is not convenient or possible. In the event that there is a justified need to use standards that have been withdrawn from use, the Laboratory may have such a standard within the scope of accreditation, provided that the text "withdrawn" must appear next to the standard's reference. The use of withdrawn standards can only be accepted if the laboratory proves that there are justified reasons, i.e. that by doing so it meets the needs of its clients or needs of state administration authorities that issue regulations and organizations that perform recognition, which means that there is an adequate explanation for the use of withdrawn standards.
 - **methods from national technical regulations** - where the technical regulation contains the complete and detailed description of the method and other elements necessary to perform the test. For methods from the national technical regulation, the name of the regulation, the number of the Official Gazette in which the regulation was published and, when appropriate, the part of the regulation in which the test procedure is described (articles of the regulation) are stated.
 - **validated methods** - non-standard methods and methods developed by the laboratory, standard methods that are used outside the intended field of application, extended or modified standard methods, as well as methods specified by manufacturer of the equipment. For validated methods, the abbreviated designation of the method as indicated in the documents of the laboratory's management system is stated, while the full name of the given method is additionally indicated as a key (Table 2), and where applicable, a reference to the document on the basis of which it was developed.

Key:

Abbreviated designation of the reference document	Name of the method / reference

Table 2. Table of validated methods

If in the column "Reference document" two or more standards are stated for a testing method, all the stated standards are applied or, if they are separated by horizontal lines, then they are used as alternatives for the given test.

- **Location label** - having in mind that a testing laboratory may have several locations where tests are performed (or some key activities related to testing), this column lists the locations or location labels (e.g. L1, L2, L3) while the key (Table 3) lists the details of the respective location(s).

Key

Location label	Location details (name and address)


Table 3. Table of laboratory locations

Additionally, if a large number of parameters/analytes (e.g. residues of pesticides, drugs, PAHs, PCBs, etc.) are determined within one test method, then they are listed in a separate table at the end of the scope of accreditation with clear identification, as given in the example below.

Ord. No.	Item of testing	Field of testing	Type of testing and/or characteristic to be measured	Measurement range (where applicable)	Reference document	Location
1.	Food of plant origin	Chemical tests	Determination of pesticide residue using GC-MS after extraction with acetonitrile and purification with the dispersive SPE-QuEChERS method <i>*** List of pesticides</i>		MEST EN 15662:2018	L1

*****List of pesticides - MEST EN 15662:2018**

Ordinal number	Pesticide	Group
1.	Bifenthrin	Pyrethroid
2.	Bitertanol	Triazoles
3.	Boscalid	Pyridinecarboxamides
4.	Chlorothalonil	Chloronitriles
5.	Chlorpyrifos	Organophosphorous
6.	Chlorpyrifos- methyl	Organophosphorous
7.	Cypermethrin	Pyrethroid
8.	Cyhalothrin	Pyrethroid
9.	DDE, p,p'-	Organochlorines
10.	DDT, p,p'-	Organochlorines

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In cases where a testing laboratory seeks accreditation for sampling that is not part of the testing method, the scope of accreditation for sampling is presented in tabular form and defined by the elements of the scope (sampling subject, type of sampling, reference document) as shown in the Table below.

In the "type of sampling" section, it is necessary to specify the testing area for which the sampling is performed, as well as the type of testing (and/or characteristic being measured) where applicable.

Sampling			
No.	Sampling Subject (Material/Product)	Type of Sampling	Reference Document

The scope of accreditation should be clearly defined with respect to the purpose of sampling (e.g., sampling for subsequent physical-chemical and microbiological analysis of water) and the type of sampling (e.g., composite, membrane filtration, etc.). **Change 4, from 03.12.2024.**

Responsibility: Head of the Department for accreditation of laboratories

4.3 EXPRESSION OF THE SCOPE OF ACCREDITATION OF CALIBRATION LABORATORIES

4.3.1 General

The abbreviated and detailed scope of accreditation of calibration laboratories is specified in the relevant Addendum to the accreditation certificate (form ZPR.01.35-1 - Addendum to the accreditation certificate for calibration laboratories).

4.3.2 Classification of calibration fields

For the purposes of expressing the scope of accreditation of calibration laboratories, ATCG established the following classification of calibration fields:

Ord. No.	Calibration field
1.	Acceleration, velocity and drift, vibrations
2.	Acoustics and ultrasound
3.	Chemistry and reference materials
4.	Density and viscosity
5.	Dimensional quantities
6.	Electrical quantities, DC/LF
7.	Electrical quantities, HF
8.	Flow (including liquid velocity)
9.	Force and power
10.	Hardness
11.	Humidity

12.	Ionizing radiation
13.	Magnetism
14.	Mass
15.	Optics
16.	Pressure and vacuum
17.	Temperature
18.	Time and frequency
19.	Volume
20.	Airflow velocity and impact energy, Charpy pendulum
21.	Other calibration fields*

*When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other fields/sub-fields of calibration that are not covered by the above classification.

4.3.3 Expression of the abbreviated scope of accreditation

The abbreviated scope of accreditation of calibration laboratories is expressed descriptively (textually) by specifying the relevant field of calibration (e.g. calibration of mass measuring instruments; calibration of time and frequency measuring instruments, etc.).

4.3.4 Expression of the detailed scope of accreditation

The detailed scope of accreditation of calibration laboratories is expressed tabularly in the manner shown in Table 4, with an indication of whether the calibration in question is performed in the laboratory or in the field.


Note: When defining the elements of the detailed scope of accreditation, the guidelines from document ILAC-G18:12/2021 were used.

Ord. No.	Calibration field	Measured quantity/ calibration item	Range of measurement	Calibration and measurement capability	Reference document	Location label

Table 4. Elements of the detailed scope of accreditation of calibration laboratories

The elements for expression of the detailed scope of accreditation shall be as follows:

- a) **Calibration field** - in this column, the relevant field of calibration is stated, whereby it is necessary to take into account the classification specified in clause 4.3.2 of this document (e.g. Temperature; Mass, etc.);
- b) **Measured quantity/calibration item** - in this column, measuring instrument or type of instrument, measuring system, measure or reference material is stated (e.g. Climate chambers up to 2000 l);
- c) **Measurement range** - in this column, the range of measurement or measurement range is stated (e.g.: 10 °C - 70 °C; 10 % RH - 50 % RH, etc.);
- d) **Calibration and measurement capability**

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- CMC is a calibration and measurement capability available to customers under normal conditions:
- (a) as described in the laboratory's scope of accreditation or
 - (b) as published in the International Bureau for Weights and Measures key comparison database (BIPM-KCDB).
- e) **Reference document** - this column contains references to relevant calibration methods, whereby they can be:
- standard methods developed by standardization organizations or other recognized organizations whose methods are generally accepted in a particular technical field.
 - For standard methods, the valid edition of the standard or other reference document is specified, indicated by the reference and the year of publication, and/or specification of principles/techniques of the calibration method
 - standard methods defined by technical regulations, if appropriate for intended application.
 - For methods defined by technical regulations, the name of the regulation, and the part of the regulation in which the calibration method is described.
 - non-standard validated methods (internal methods developed by the laboratory, extended or modified standard methods, if appropriate for intended application).
 - For non-standard methods, the reference of the valid edition of the internal document describing the method is stated, while the name of the document and relevant data/reference is indicated as a key (as shown in Table 5). If in the column "Calibration method" two or more reference documents are stated for the same calibration item, all the stated documents are applied or, if they are separated by horizontal lines, then they are used as alternatives for the given calibration.

Key:

Abbreviated designation of the reference document	Name of the method / reference

Table 5. Table for validated methods

- f) **Location label** - having in mind that a calibration laboratory may have several locations where calibration activities are performed, this column lists the locations or location labels (e.g. L1, L2, L3) while the key (Table 6) lists the details of the respective location(s).

Key:

Location label	Location details (name and address)


Table 6. Table of laboratory locations

Responsibility: Head of the Department for accreditation of laboratories

4.4 EXPRESSION OF THE SCOPE OF ACCREDITATION OF MEDICAL LABORATORIES (according to the standard EN ISO 15189)

4.4.1 General

The abbreviated and detailed scope of accreditation of medical laboratories (accredited according to EN ISO 15189 standard) is specified in the corresponding Addendum to the accreditation certificate (form ZPR.01.39 - Addendum to the accreditation certificate for medical laboratories).


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4.4.2 Classification of fields and types of medical examination

For the purpose of expressing the scope of accreditation of medical laboratories, ATCG established the following distinction of fields and types of medical examination:

a) Fields of medical examination, with subfields (or techniques) of examination

Ord. No.	Field of medical examination	Subfields (or techniques) of examination
1.	Medical biochemistry	Medicinal chemistry
		Medical biochemistry
		Hematology and coagulation
		Immunochemistry
2.	Medical microbiology	Bacteriology
		Mycology
		Virology
		Parasitology
		PCR microbiology (molecular)
3.	Immunology	Immunity
		Immunocytochemistry
		Immunogenetics
		Immunohypersensitivity
		Immunopathology
4.	Transfusion medicine	Blood typing and antibody detection
		Collection of blood from donors
		Processing of blood and blood components
		Accommodation, distribution and transport of blood and blood components
5.	Medical cytology	
6.	Pathology	Anatomical pathology (Cytopathology, Dermatopathology, Histopathology, Neuropathology, Pulmonary pathology, Kidney pathology, Surgical pathology)
		Clinical pathology (Hematopathology)
		Molecular pathology
		Oral and maxillofacial pathology
7.	Radiology	Radiography (x-ray)
		Ultrasound
		Computed tomography (CT, scanner)
		Magnetic resonance imaging (MRT)

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		Nuclear medicine
8.	Medical pharmacology	
9.	Forensic medicine	Forensic genetics
		Forensic pathology
		Forensic toxicology
10.	Point-of-care testing POCT (ISO 22870)	
11.	Medical genetics	Clinical genetics
		Metabolic/biochemical genetics
		Cytogenetics
		Oncogenetics
		Molecular genetics
12.	Medical toxicology	
13.	Sampling for the purposes of medical testing	
14.	Other fields of medical examination*	

**When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other fields/sub-fields that are not included in the above classification.*

b) Types of medical examinations (in accordance with the definition of medical laboratories - clause 3.11 of the standard EN ISO 15189:2016):

Ord. No.	Types of medical tests
1.	Biological examinations
2.	Microbiological examinations
3.	Immunological examinations
4.	Chemical examinations
5.	Immuno-hematological examinations
6.	Hematological examinations
7.	Biophysical examinations
8.	Cytological examinations
9.	Pathological examinations
10.	Genetic examinations
11.	Other types of medical examinations*

**When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other types of medical examinations that are not included in the above classification.*

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4.4.3 Expression of the abbreviated scope of accreditation

The abbreviated scope of accreditation of medical laboratories is expressed descriptively (textually) by stating the field of medical examinations in relation to the item of examination (material/sample) or object of the examination (e.g. Biochemical tests of human clinical samples).

4.4.4 Expression of the detailed scope of accreditation

The detailed scope of accreditation of medical laboratories is expressed tabularly in the manner shown in Table 7, with an indication of whether the examination in question is performed in a laboratory or in the field.

Note: When defining the elements of the detailed scope of accreditation, the guidelines from document ILAC-G18:12/2021 were used.

The detailed scope of accreditation is expressed tabular in the manner shown in Table 7, for each individual location of the laboratory where the examination is performed and with an indication of whether the examinations are performed in the laboratory or in on-site. Description of the scope of accreditation of medical laboratories is prescribed by document EA-4/17 M:2022.

If a medical laboratory is accredited for the collection of primary samples, ATCG will clearly identify this activity within the scope of accreditation. **Change 5, from 03.12.2024.**


No.	Field and/or Subfield	Type of examination/ Sampling	Scope of testing/ sampling	Examination technique/ sampling	Reference document for examination/ sampling	Location
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Table 7. Detailed scope of accreditation of medical laboratories

The elements for expression of the scope of accreditation shall be as follows:

- a) **Item of examination, i.e. material/sample** - the object of the examination is stated (e.g.: Blood; Serum; Plasma, etc.);
- b) **Field and/or Subfield** - the field and, where applicable, the subfield of medical examination is stated in accordance with the classification described in the previous text (e.g. Medical Microbiology / Parasitology; Anatomical pathology/Histopathology etc).
Type of examination - the type of medical examinations is stated in accordance with the classification described in the previous text (e.g. Microbiological examinations; Hematological examinations, etc.)
- c) **Measured characteristic and/or examination technique** - the characteristic that is measured and the technique used to conduct the examinations are stated (e.g.: Determination of albumin concentration/ Spectrophotometric method - BCP test). Furthermore, where applicable, the detection limit (L.D.), measurement uncertainty (U) and measurement range (e.g. L.D=0.0-100g/L; U=0.45) are also indicated here; It is possible to specify an instrument/analyzer used in accordance with the manufacturer's instructions/protocol, so that the reference to the instrument (manufacturer's name and version/type) can provide a unique identification of the testing method. **Change 2, from 27.09.2024.**
- d) **Reference document** (national technical regulation, standard method, validated method) – states references for:

Methods from the national technical regulations (ordinances etc.), where the technical regulation contains a complete and detailed description of the method and other elements necessary for performing the medical examination. For methods from the national technical regulation, the name of

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the regulation, the number of the Official Gazette in which the regulation was published and, when appropriate, the part of the regulation in which the examination procedure is described (articles of the regulation) are indicated

Standard Methods – methods developed by standardization organizations or other recognized organizations whose methods are generally accepted. For standard methods, the valid edition of the standard is specified, indicated by the reference and the year of publication, and when appropriate, the part of the standard in which the examination procedure is described (clauses of the standard) is additionally specified.

Note: In accordance with the requirements of the EN ISO/IEC 17025:2018 and EN ISO 15189:2016 standards, the laboratory shall ensure the use of the latest valid edition of the standard, unless it is not convenient or possible. In the event that there is a justified need to use standards that have been withdrawn from use, the Laboratory may have such a standard within the scope of accreditation, provided that the text "-withdrawn" must appear next to the standard's reference. The use of withdrawn standards can only be accepted if the laboratory proves that there are justified reasons, i.e. that by doing so it meets the needs of its clients or needs of the state administration authorities that issue regulations and of organizations that perform recognition, which means that there is an adequate explanation for the use of withdrawn standards.

Validated methods - methods developed by the laboratory, non-standard methods and standard methods that are used outside the intended field of application, extended or modified standard methods, as well as methods specified by manufacturer of the equipment. In these cases, and whenever it is applicable, in the key below the table for detailed scope of accreditation, it is necessary to indicate the abbreviated designation of the method and the full name of the method and the reference/name of the document that was used as a basis for its development (Table 8).

Key:

Abbreviated designation of the method:	Name of the internal method / references

Table 8

e) **Location label** - In case that the medical laboratory has several locations where medical examinations are performed, in the location label column: an abbreviated designation is indicated (e.g.: L1 for Location 1, L2 for Location 2, etc.) that identifies the place of examination (i.e. the location where the examination is performed), while the details of that location (name, address, phone/fax, e-mail) are listed in a separate table:


Location

Location details (name, address, telephone/fax, e-mail)	Location label

Table 9. Location details

In case the medical laboratory performs point-of-care testing (POCT), the elements for expressing the scope also include information about the POCT location:

Ord. No.	Field and/or subfield	Type of examination	Test item (material/sample)	Measured characteristic and/or the examination technique and/or equipment (instrument)	Reference document	POCT location ¹ Place of providing POCT ² Cluster ³

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¹ Building (e.g., hospital) where POCT is performed

² Department, clinics, emergency rooms, etc., where POCT services are provided

³ Grouping of POCT service locations, such as departments and clinics, where critical variables like IT interfaces and the purpose of POCT (e.g., emergency care) are the same Change 3, from 27.09.2024

Responsibility: Head of the Department for accreditation of laboratories

4.5 EXPRESSION OF THE SCOPE OF ACCREDITATION OF INSPECTION BODIES

4.5.1 General

The abbreviated and detailed scope of the accreditation of inspection bodies is specified in the relevant Addendum to the accreditation certificate (form ZPR.01.36-1 - Addendum to the accreditation certificate for inspection bodies).

Note: Within the Addendum to the accreditation certificate, and in accordance with the guidelines from document ILAC-G28:07/2018, in addition to other information, the type of inspection body (A, B or C) is stated, indicating the degree of its independence (in accordance with Annex A of the standard EN ISO/IEC 17020:2013).

4.5.2 Classification of items and types of inspection

For the purposes of expressing the scope of accreditation of inspection bodies, ATCG established the following classification of items and types of inspection:

a) inspection items, with subtypes of inspection items

Ord. No.	Inspection item	Subtypes of inspection items
1.	Pressure equipment and gas installations	Pressure equipment
		Gas appliances and installations
		Equipment for LPG/CPG vehicles
2.	Transportable pressure equipment	
3.	Vehicles (and equipment) for the transport of dangerous goods on roads, railways and waterways	ADR equipment (packaging)
		ADR road vehicles
		RID
		ADN
4.	Measuring instruments (gauges)	Water meters
		Gas meters and volume conversion devices
		Electricity meters and measuring transformers
		Thermal energy meters
		Measuring systems for continuous and dynamic measurement of quantities of liquids other than water
		Mass scales




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		Taximeters and tachographs
		Materialized measures
		Dimensional measuring instruments
		Measurements of chemical quantities (Exhaust gas analyzers, Opacimeters, Ethyl meters)
		Pressure gauges
		Measurements of optical quantities
		Force gauges
		Moisture meters
		Protein analyzers
		Automatic liquid level gauges
		Measurement instruments incorporated in medical devices
5.	Vehicles and traffic equipment	Vehicles
		ATP (transport of perishable goods)
		Traffic signs
6.	Petroleum and chemistry	Ores
		Solid fuels
		Liquid fuels of petroleum origin (petroleum derivatives and LPG)
		Gas fuels
		Chemicals
		Cosmetic products
		Biocides
		Aerosol dispensers
		Manure
		Rubber and plastic
7.	Lifts and lifting mechanisms	Lifts and lift components (for transporting people and/or goods)
		Escalators and conveyor belts
		Stair lifts and inclined platforms
		Lifting mechanisms
8.	Cable cars for transporting people	
9.	Living and working environment	Noise
		Working environment (microscope, brightness, noise level)
		The field of occupational safety
10.	Agricultural and food products	Field, fruit and vegetable crops and their products
		Livestock and products of animal origin
		Animal feed
		Alcohol and alcoholic products
		Products from organic production



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11.	Equipment used in a potentially explosive atmospheres	
12.	Personal protective equipment	
13.	Constructions and construction products	Construction products
		Constructions
14.	Textiles, leather, clothing	Textiles and textile products, including clothing
		Leather and leather products
		Shoes
15.	Electrical products and equipment, telecommunications, electronics	Low-voltage electrical installations, including lightning protection installations
		Electrical appliances for household and similar use
		Protective means and equipment
		Telecommunication installations and equipment (including radio and TT equipment)
		Electronic devices and equipment
16.	Installations and devices for fire and explosion protection	Hydrant network installations for fire extinguishing
		Mobile fire extinguishers
		Installations and devices for automatic fire detection and alarm
		Fire extinguishing installations and devices
		Installations and devices for the detection of explosive and flammable gases
		Smoke and heat removal installations
		Installations and devices in explosion hazard zones
17.	Furniture and wood	Wood and wood products
		Furniture
18.	Metallic and non-metallic materials	Metal materials
		Non-metallic materials
		Welding and qualification of welding technology
		Brazing and qualification of brazing technology
		NDT
		Thermography
19.	Household and leisure equipment (including children's playgrounds)	Toys
		Sports equipment
		Recreational vessels

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		Children's playgrounds
20.	Machines, plants, equipment	Machines (household appliances, industrial machines)
		Industrial fittings
		Hydraulics, pneumatics
		Thermal turbomachines
		Hot water boilers (oil or gas fueled)
		Electric power plants
		Nuclear plants
21.	Explosives for civil use	
22.	Medicines	
23.	Medical devices	
24.	Eco-design	
25.	Other inspection items*	

* When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other inspection items that are not included in the above classification.


b) types of inspection:

Ord. No.	Types of inspection
1.	Document inspection
2.	Inspection before putting into use
3.	In-use inspection
4.	Inspection of repairs and modifications
5.	Inspection before putting into reuse
6.	Periodic inspection
7.	Extraordinary inspection
8.	Safety inspection
9.	Visual inspection
10.	Quantitative inspection
11.	Qualitative inspection
12.	Inspection of characteristics (e.g. dimensions, adaptability, impermeability...)
13.	Process inspection (e.g. production, packaging, labeling and marking, storage, loading, transshipment, unloading, etc.)
14.	Inspection of provision of services
15.	Sampling for inspection purposes
16.	Other types of inspection*

*When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other types of inspection that are not included in the above classification.

4.5.3 Expression of the abbreviated scope of accreditation

The abbreviated scope of accreditation of inspection bodies is expressed descriptively (textually) by stating the type of inspection in relation to the item of inspection (e.g. Periodic inspection of lifts for transport of persons; Quantitative inspection of petroleum and petroleum products, etc.).

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4.5.4 Expression of the detailed scope of accreditation

The detailed scope of accreditation of inspection bodies is presented tabularly in the manner shown in Table 10, with an indication of whether the inspection in question is performed in the inspection body or in the field.

Note: When defining the elements of the detailed scope of accreditation, the guidelines from document ILAC-G28:07/2018 were used.

Ord. No.	Item of inspection	Type of inspection – characteristics that are inspected	Reference document	Location label

Table 10. Elements of the detailed scope of accreditation of inspection bodies

The elements for expressing the detailed scope of accreditation shall be as follows:

- a) **Item of inspection** - in this column, the inspection item is stated, whereby it is necessary to take into account the classification specified in clause 4.5.2 of this document (e.g. petroleum and petroleum products, etc.). When specifying the item of inspection, it is necessary to describe the object of inspection in as much detail and precision as possible. If it is a product, it is necessary, when applicable, to indicate its belonging to a wider group and subgroup of products, as well as the range of products (e.g. Lifts for vertical transport of persons/Electrically powered lifts/Maximum load capacity up to 6 persons). If it is a process, it is necessary to specify the process and the product that is the result of that process (e.g. Inspection of factory production / Glass for building structures). If it is an installation, it is necessary to specify the installation in question (e.g. premises for farming of animals).
- b) **Type of inspection – characteristics that are inspected** - in this column, the type of inspection is stated, whereby it is necessary to take into account the classification specified in clause 4.5.2 of this document (e.g. In-use inspection, etc.), and, where applicable, the characteristics of the inspection item that are inspected;
- c) **Reference document** - this column contains references to relevant inspection methods, whereby they can be:
 - **standard methods** - methods developed by standardization organizations or other recognized organizations whose methods are generally accepted in a particular technical field. For standard methods, the valid edition of the standard is specified, indicated by the reference and the year of publication, and when appropriate, the part of the standard in which the inspection procedure is described (clauses of the standard) is additionally specified.
Note: The inspection body shall ensure the use of the latest valid editions of standards, unless it is not convenient or possible. In the event that there is a justified need to use standards that have been withdrawn from use, the inspection body may have such a standard within the scope of accreditation, provided that the text "withdrawn" must appear next to the standard's reference. The use of withdrawn standards can only be accepted if the inspection body proves that there are justified reasons, i.e. that by doing so it meets the needs of its clients or of the state administration authorities that issue regulations and organizations that perform recognition, meaning if there is an adequate explanation for the use of withdrawn standards.
 - **methods from national technical regulations**, where the technical regulation contains a complete and detailed description of the method and other elements necessary for performing

the inspection. For methods from a national technical regulation, the name of the regulation, the number of the Official Gazette in which the regulation was published and, when appropriate, the part of the regulation in which the inspection procedure is described (articles of the regulation) are indicated.

- **validated methods** - non-standard methods and methods developed by the inspection body, standard methods that are used outside the intended field of application, extended or modified standard methods, as well as methods specified by manufacturer of the equipment. For validated methods, the abbreviated designation of the method as defined in the documents of the inspection body's management system is stated, while the full name of the given method is additionally indicated as a key (Table 11), and where applicable, a reference to the document on the basis of which it was developed.

Key:

Abbreviated designation of the reference document	Name of the method / reference

Table 11. Table of validated methods

If two or more reference documents are listed in the "Reference document" column for the inspection method in question, all of the reference documents are applied or, if they are separated by horizontal lines, then they are used as an alternative for the given inspection.

- d) **Location label** - having in mind that an inspection body may have several locations where inspections are performed (or some key activities related to inspection), this column lists the locations or location labels (e.g. L1, L2, L3) while the key (Table 12) lists the details of the respective location(s).

Key

Location label	Location details (name and address)

Table 12. Table of inspection body's locations

Responsibility: Head of the Department for accreditation of inspection bodies


4.6 EXPRESSION OF THE SCOPE OF ACCREDITATION OF CERTIFICATION BODIES FOR CERTIFICATION OF PRODUCTS

4.6.1 General

The abbreviated and detailed scope of the accreditation of product certification bodies is specified in the relevant Addendum to the accreditation certificate (form ZPR.01.37-1 - Addendum to the accreditation certificate for product certification bodies).


4.6.2 Classification of certification fields

For the purposes of expressing the scope of accreditation of product certification bodies, ATCG established the following classification of certification fields (and sub-fields):

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Ord. No.	Product certification fields	Product certification sub-fields
1.	Electrical products and equipment, telecommunications, electronics	Electrical equipment intended for use within certain voltage limits
		Equipment that may cause electromagnetic interference
		Radio equipment and telecommunication terminal equipment
2.	Lifts and lifting mechanisms	Lifts and lift components (for transporting people and/or goods)
		Escalators and conveyor belts
		Stairlifts and inclined platforms
		Lifting mechanisms
3.	Cable cars for transporting people	
4.	Building materials, products and structures	Sub-fields or construction product areas according to the classification given in Annex IV of Regulation (EU) No. 305/2011
		Concrete
5.	Equipment used in a potentially explosive atmospheres	
6.	Explosives for civil use and pyrotechnic articles	
7.	Personal protective equipment	
8.	Machines, plants, equipment	Machinery (including industrial machinery)
		Hot water boilers
		Appliances burning gaseous fuels
9.	Equipment under pressure	Pressure equipment
		Transportable pressure equipment
		Simple pressure vessels
10.	Measuring instruments	Measuring instruments
		Non-automatic weighing instruments
11.	Medical devices	Medical devices
		Active implantable medical devices
		In-vitro diagnostic medical devices
12.	Organic production	Organic plant production, including wild plant harvesting
		Organic animal husbandry and organic animal products
		Processing of organic products
		Organic group production
13.	Products with a designation of geographical origin	
14.	Household and leisure equipment (including children's playgrounds)	Toys
		Recreational vessels
		Children's playgrounds
15.	Other product certification fields*	

**When defining the requested (sought) scope of accreditation, the applicant for accreditation may, where applicable, specify some other product certification fields that are not included in the above classification.*

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4.6.3 Expression of the abbreviated scope of accreditation

The abbreviated scope of accreditation of product certification bodies is expressed descriptively (textually) by specifying the field (subfield) of product certification (e.g. Certification of toys, Certification of simple pressure vessels...).

4.6.4 Expression of the detailed scope of accreditation

The detailed scope of accreditation of product certification bodies is presented tabularly in the manner shown in Table 13, whereby all locations of a certification body shall be listed.

Ord. No.	Certification field	Product/Process/service	Conformity assessment procedure (where applicable)	Reference document	Location label

Table 13. Detailed scope of accreditation of product certification bodies


The elements for expressing the detailed scope of accreditation are as follows:

- **Certification field** (e.g. electrical products and equipment, telecommunications, electronics, construction products, materials and structures)
- **Product/Process/Service**, a detailed and precise description of the object of certification is specified (e.g. electrical equipment intended for use within certain voltage limits, aggregate, concrete...); based on EA 2/17: products/category – family – homogeneous groups of products (according to NANDO classification where possible) is stated; if there are restrictions in the implementation of certification within the category or group of products, they are specified in the scope of accreditation. **Change 8, from 25.04.2025.**
- **Conformity assessment procedure**, the point, member of the technical regulation i.e. the name of the module from technical regulation or ACVP system in which the conformity assessment procedure is described, shall be stated **Change 8, from 25.04.2025.** (e.g. Article 13 of the Rulebook on electrical equipment for use within certain voltage limits, AVCP 2+);
- **Reference document**: the documents in which the product certification schemes and/or the documents in which the product requirements are given (e.g. standards referred to in the technical regulation containing the product certification requirements), i.e. requirements for product certification. Reference documents can be laws, technical regulations, standards, documents developed with the participation of interested parties, etc., and where applicable (if the reference document specifies conformity assessments procedure).

Where possible, the accreditation scope for notification purposes should use the same wording as used by NANDO. Additionally, the accreditation scope can also include other information if required by the Notifying Authority, applicable legislation or mandatory documents if deemed necessary due to other circumstances. **Change 8, from 25.04.2025.**

If the product certification is performed at several locations, it is necessary to provide information on the locations where key activities related to product certification are carried out.

All locations where activities are performed within the scope of the certification body's accreditation shall be specified, with the addition of "and on-site", where applicable.

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Note 1: On-site certification is the certification at the client's location, i.e. location where the object of certification is located, not the location of the certification body.

Note 2: Activities within the certification process that are carried out on-site or at the premises of users of the objects of certification are not considered as key activities.

Scope of accreditation of certification bodies for assessment and verification of constancy of performance of construction products:

No.	Certification field	Product/Group of products	Procedure AVCP	Reference documents	Location
1.	Building products, materials and constructions	Product/Product group(s) and, if applicable, the intended use of the construction product	applicable AVCP procedure	Technical regulation and (where applicable) the Montenegrin standard referred to in the technical regulation or the Montenegrin technical specification in accordance with which the AVCP system is implemented	


Change 6, from 03.12.2024.

When defining the scope of certification bodies for the certification of products in organic production, the categories of products must be specified in accordance with the Law on Organic Production ("Official Gazette of Montenegro," No. 53/14), the Rulebook on Detailed Conditions and Rules for Organic Plant and Livestock Production, and the Rulebook on Detailed Conditions and Rules for the Processing, Packaging, Transport, and Storage of Organic Products ("Official Gazette of Montenegro," No. 83/16).

For certification bodies involved in the certification of protected products, the scope of accreditation must include product categories as defined in the Law on Quality Schemes for Agricultural and Food Products ("Official Gazette of Montenegro," No. 22/17).

An example of how the scope of accreditation should be presented is provided in the table below:

Field of Certification	Product / process / service	Reference document
Organic production	Plant production products	The Law on Organic Production The Rulebook on Detailed Conditions and Rules for Plant and Livestock Organic Production The Rulebook on Detailed Conditions and Rules for the Processing, Packaging, Transport, and Storage of Organic Products
Organic production	Animal production products	The Law on Organic Production The Rulebook on Detailed Conditions and Rules for Plant and Livestock Organic Production The Rulebook on Detailed Conditions and Rules for the Processing, Packaging, Transport, and Storage of Organic Products

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Organic production	Processed products	The Law on Organic Production The Rulebook on Detailed Conditions and Rules for Plant and Livestock Organic Production The Rulebook on Detailed Conditions and Rules for the Processing, Packaging, Transport, and Storage of Organic Products
Certification of agricultural/food products with a protected geographical indication	Meat and meat products Cheese Eggs, honey, and other dairy products Fish, shellfish, crustaceans, and their products	The Law on Quality Schemes for Agricultural and Food Products (Official Gazette of Montenegro, No. 22/17)
Certification of agricultural/food products with a protected designation of origin	Meat and meat products Cheese Eggs, honey, and other dairy products	The Law on Quality Schemes for Agricultural and Food Products (Official Gazette of Montenegro, No. 22/17)
Certification of agricultural/food products with traditional specialties guaranteed	Meat and meat products Cheese Eggs, honey, and other dairy products	The Law on Quality Schemes for Agricultural and Food Products (Official Gazette of Montenegro, No. 22/17)

Change 7, from 03.02.2025.

Responsibility: Head of the Department for accreditation of certification bodies

4.7 EXPRESSION OF THE SCOPE OF ACCREDITATION OF CERTIFICATION BODIES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

4.7.1 General notes

In the following text, the classification from NACE Rev. 2 is used for classification of economic activities, i.e. sectors according to the statistical classification of economic activities from the corresponding IAF MD and IAF ID documents.


When defining the scope of accreditation for QMS and EMS certification, IAF ID 1:2020 is applied. Food chain category classification - letter classification for categories A to K, i.e. technical areas of the food chain, is in accordance with the classification defined in Annex A of ISO/TS 22003:2016.

4.7.2. Contents of the scope of accreditation of management system certification bodies

The abbreviated scope of accreditation is expressed descriptively, by stating the type of management system and the document containing the requirements for management system certification. The abbreviated scope of accreditation is also given in English language (in italics at the end of each presentation of the specified type of management system and the document containing the requirements for management system certification), for example: (certification of quality management system according to MEST ISO 9001:2016 / certification of quality management systems according to ISO 9001:2015)

The detailed scope of accreditation is presented in a table for each individual type of management system certification, indicating the locations where the following activities are performed: policy formulation; process and procedure development; recruiting and registering auditors and managing their training; constant monitoring of the work of auditors; review of certification applications; appointing a team of auditors; audit management; adoption of audit reports and decision-making on certification, by stating titles and references of management system standards and designations of technical areas, as well as stating relevant codes from NACE Rev. 2 for each technical area.

In scopes of accreditation of certification bodies for certification of quality management systems, it is stated that the certification body is accredited according to MEST EN ISO/IEC 17021-1:2018 and

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according to EN ISO/IEC 17021-3:2020.

In scopes of accreditation of certification bodies for certification of environmental management systems, it is stated that the certification body is accredited according to MEST EN ISO/IEC 17021-1:2018 and according to EN ISO/IEC 17021-2:2020.

In scopes of accreditation of certification bodies for certification of occupational health and safety management systems, it is stated that the certification body is accredited according to MEST EN ISO/IEC 17021-1:2018 and according to ISO/IEC TS 17021-10:2018.

In scopes of accreditation of certification bodies for certification of food safety management systems, it is stated that the certification body is accredited according to MEST ISO/IEC 17021-1:2015 and according to METI ISO/TS 22003:2016

In scopes of accreditation of certification bodies for certification of information security management systems, it is stated that the certification body is accredited according to EN ISO/IEC 17021-1:2018 and according to ISO/IEC 27006:2015, ISO/IEC 27006:2015/Amd.1:2020.

For the certification of quality management systems according to EN ISO 9001, environmental management systems according to the EN ISO 14001, occupational health and safety management systems according to the EN ISO 45001, the classification of technical areas is done according to IAF ID 1:2020.

For the certification of information security management systems according to the MEST ISO/IEC 27001, technical areas are not classified. The scope of accreditation according to this standard is expressed only by reference to the standard and is valid for all technical areas.

4.7.3 Areas of management system certification

For the certification of quality management systems according to EN ISO 9001 and the certification of environmental management systems according to the EN ISO 14001, the classification of technical areas is carried out according to IAF ID 1:2020, while for certification of occupational health and safety management systems according to the EN ISO 45001, the classification is carried out according to IAF ID 1:2020, taking into account Appendix B of IAF MD 22:2019.

Table 14 shows the certification areas in accordance with IAF ID 1:2020.

EA Code	Field of activity	NACE Rev. 2 Code*
1.	Agriculture, hunting and forestry. Fishing.	01, 02, 03
2.	Mining and quarrying	05, 06, 07, 08, 09
3.	Production of food products, beverages and tobacco	10, 11, 12
4.	Production of textiles and textile products	13, 14
5.	Leather processing and production of leather goods	15
6.	Wood processing and wood products	16
7.	Production of pulp, paper and paper products	17
8.	Publishing activity	58.1, 59.2
9.	Printing and service activities related to printing. Playback of recorded media.	18
10.	Production of coking products. Production of petroleum products.	19
11.	Preparation of nuclear fuel	24.46
12.	Production of chemicals, chemical products and artificial and synthetic fibers, except for the production of pharmaceutical products, medical chemicals and herbal preparations	20
13.	Production of pharmaceutical products, medical chemicals and herbal preparations	21
14.	Production of rubber and plastic products	22



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15.	Production of products from other non-metallic minerals, other than the production of cement, lime and gypsum and the production of products from concrete, cement or plaster	23 (except 23.5 and 23.6)
16.	Production of cement, lime and gypsum. Production of concrete, cement or plaster products	23.5 and 23.6
17.	Production of basic metals and fabricated metal products	24 (except 24.46), 25 (except 25.4), 33.11
18.	Production of machinery and equipment	25.4, 28, 30.4, 33.12, 33.2
19.	Production of electrical and optical equipment	26, 27, 33.13, 33.14, 95.1
20.	Shipbuilding and repair of ships and boats	30.1, 33.15
21.	Production of air and space aircraft	30.3, 33.16
22.	Production of motor vehicles, trailers and semi-trailers. Production of railway and tram locomotives and rolling stock. Production of motorcycles and bicycles. Production of other means of transport.	29, 30.2, 30.9, 33.17
23.	Furniture manufacturing. Production of other products that are not precisely specified in the classification.	31, 32, 33.19
24.	Recycling	38.3
25.	Production, transmission and distribution of electricity	35.1
26.	Gas production and distribution of gaseous fuels through pipe systems	35.2
27.	Collection, purification and distribution of water. Production and supply of steam and hot water	35.3, 36
28.	Construction	41, 42, 43
29.	Wholesale and retail trade. Repair of motor vehicles, motorcycles and personal and household goods	45, 46, 47 95.2
30.	Hotels and restaurants	55, 56
31.	Traffic, storage and communications	49, 50, 51, 52, 53, 61
32.	Financial intermediation. Real estate activities. Rental of machines and equipment without operator and rental of personal and household goods.	64, 65, 66, 68 77
33.	Information technology and related activities	58.2, 62, 63.1
34.	Research and development. Architectural and engineering activities and technical advice	71, 72, 74 (except 74.2 and 74.3)
35.	Other business activities except architectural and engineering activities and technical advice	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82
36.	State administration and defense. Compulsory social insurance	84
37.	Education	85
38.	Health and social work	75, 86, 87, 88
39.	Other communal, social and personal services	37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96

Table 14 – Certification areas according to IAF ID 1:2020

*NACE Code - Designation of the category of the field of activity, that is, the sector according to the statistical classification of economic activities (according to the document REGULATION (EC) No 1893/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains)

The abbreviated scope of accreditation of certification bodies for quality management system certification is expressed descriptively (textually) as follows: "Certification of Quality Management Systems".

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The detailed scope of accreditation is expressed tabularly in the manner shown in Table 15, whereby all locations of the certification body where the certification procedure is carried out are listed.

EA Code	Name and description of activity	NACE Rev. 2 Codes	Location

Table 15. Detailed scope of accreditation of management system certification certification bodies

4.7.4 Food safety management systems

For the purposes of expressing the scope of accreditation of certification bodies for certification of food safety management systems (MEST EN ISO 22000 standard), ATCG has established the following distinction of technical areas (fields of activity), which is in accordance with Annex A of the document METI TS ISO/TS 22003:2016

The abbreviated scope of accreditation of certification bodies for certification of food safety management systems is expressed descriptively (textually) as follows: "Certification of food safety management systems".

The detailed scope of accreditation is expressed tabularly in the manner shown in Table 16, whereby all the locations of the certification body where some of the key activities that have a significant impact on the certification procedure are carried out (determining the policy of the certification body, implementation of processes and/or procedures for development, initial approval (inclusion in the register) of personnel that perform audits during the certification process, review of the application for certification, appointment of audit teams, management of surveillance and recertification audits, review of the final report on the performed audit in the certification process and making/approving the decision on management system certification, etc.).

<i>CLUSTER^a</i>	Category		Subcategory	
Farming	A	Farming of Animals	I	Farming of Animals for Meat/ Milk/ Eggs/Honey
			II	Farming of Fish and Seafood
	B	Farming of plants	I	Farming of Plants (other than grains and pulses)
			II	Farming of Grains and Pulses
Food and feed processing	C	Food Manufacturing	I	Processing of perishable animal products
			II	Processing of perishable plant products
			III	Processing of perishable animal and plant products (mixed products)

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			IV	Processing of ambient stable products
	D	Animal feed production	I	Production of Feed
			II	Production of pet food
Catering	E	Catering		
Retail, transport and storage	F	Distribution	I	Retail / Wholesale
			II	Food Broking / Trading
	G	Provision of transport and storage services	I	Provision of transport and storage services for perishable food and feed
			II	Provision of transport and storage services for ambient stable food and feed
Auxiliary services	H	Services		
	I	Production of food packaging and packaging materials		
	J	Equipment manufacturing		
Biochemicals	K	Production of (bio)chemicals		


Table 16. Detailed scope of accreditation of certification bodies for certification of food safety management systems

4.7.5 Information security management systems

For the purposes of expressing the scope of accreditation of certification bodies for certification of information security management systems (ISO/IEC 27001), ATCG has determined that the certification applies to all technical areas and activities.

The abbreviated scope of accreditation of certification bodies for certification of information security management systems is expressed descriptively (textually) as follows: "Certification of information security management systems".

In the detailed scope of accreditation of certification bodies for certification of information security management system certification, it is stated that the certification body is accredited according to MEST EN ISO/IEC 17021-1:2018 and according to ISO/IEC 27006:2015 and ISO/IEC 27006:2015/Amd.1:2020

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4.7.6 Occupational health and safety management systems

For the purposes of expressing the scope of accreditation of certification bodies for certification of occupational health and safety management systems, the abbreviated scope of accreditation is expressed descriptively (textually) as follows: "Certification of occupational health and safety management systems".

The detailed scope of accreditation is presented tabularly in the manner shown in Table 17, whereby all locations of the certification body where the certification procedure is carried out are listed.

The abbreviated scope of accreditation of certification bodies for certification of information security management systems is expressed descriptively (textually) as follows: "Certification of information security management systems".

EA Code	Name and description of activity	NACE Rev. 2 Codes	Location

Table 17. Detailed scope of accreditation of certification bodies for certification of occupational health and safety management systems

Identification of activities is based on IAF ID 1:2020 taking into account Appendix B of IAF MD 22:2019

Responsibility: Head of the Department for accreditation of certification bodies

5. FORMS

This procedure has no accompanying forms.