SNAS SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

FIELD AND SCOPE OF ACCREDITATION OF LABORATORIES FIELD AND PROFICIENCY TESTING PROVIDERS

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CONTENT

1 INTRODUCTION

The purpose of this MSA is to provide information how to define accreditation field and accreditation scope. MSA is applicable for all types of laboratories being accredited or already accredited as well as for proficiency testing providers and it is obligatory for SNAS, applicants for accreditation and for assessors of laboratories.

2. ABBREVIATIONS USED

Abbreviations:

ILAC	-	International Laboratory Accreditation Cooperation
MSA	-	Methodical Guideline for Accreditation
MS	-	Management System
PT	-	Proficiency testing

Terms:

Field of Accreditation
is an informative definition entity performance which are accredited or accreditation of which is sought.

Scope of Accreditation
is a detailed description of performance the entity is accredited for.

Specification of activity
is a performance scope the entity applies for; as for form it is identical with the accreditation scope; however, as for their content, they can differ each other.

Type of laboratory
Classification of laboratory according to competence for performing modification and validation of testing and/or calibration methods and to develop new methods within the accredited activities.

List of accredited activities
is the "Scope of Accreditation" encompassing performances covered by flexible scope and being managed independently by the accredited conformity assessment body/laboratory.
(Note: Further on the "list of accredited performance" is stated as "List".)

3. RELATED DOCUMETS

ISO/IEC 17000: Conformity assessment. Vocabulary and general principles.
ISO/IEC 17011: Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies
Standards of ISO 80000 series - from part 1 to part 14: Quantities and Units.

ILAC-P14: ILAC Policy for Uncertainty in Calibration
ILAC-G18: Guidlines for the formulation of Scopes of accreditadation for Laboratories.
EA-2/15 M: EA Requirements for the Accreditation of Flexible Scopes (MSA-07: EA requirements for the accreditation of flexible scopes.)
EA-2/18:INF:Guidelines for Accreditation Bodies on The Contents of the Scopes of Accreditation for Proficiency Testing Providers
EA-4/02 M:Evaluation of the Uncertatinty of Measurement in Calibration. (MSA-L/12 Vyjadrovanie neistôt merania pri kalibrácii.)
EA-4/17 M: Position Paper on the description of scopes of accreditation of medical laboratories
Act No. 71/1967 Coll. on Administrative Proceedings (Administrative Code) as Amended
Act No. 505/2009 Coll. on Accreditation of Bodies Responsible for Conformity Assessment and on Amendment of Certain Acts (further on only "Act")
STN 01 0115: 2011. Terminology in Metrology
PL-34: SNAS Policy for Uncertainty in Calibration

4 ACCREDITATION SCOPE (PERFORMANCE SPECIFICATION) OF A LABORATORY AND PROFICIENCY TESTING PROVIDER

Performance specification (accreditation scope) is defined according to individual types of laboratories/entities and performances in compliance with the tables shown in the following Annexes:

Kind of Body/Laboratory	Activities	Annex of MSA-L/01
Calibration Laboratory	Calibration of instruments and reference materials, calibration for the purpose of verification of legal measuring instruments, measurement of physical quantities (subject to the conditions set out in the Annex A1). Expressing opinions and interpretations	Annex A1
Testing Laboratory	Tests, measurements, analyses of various material, matrixes, testing of instruments, , sampling, giving opinions and interpretations	Annex A2
Medical Laboratory	Analyses, examinations of biological materials taken from the human organism and sampling	Annex A3
PT provider	PT providing and PT evaluation	Annex A4

A detailed guideline for definition of performance specification (accreditation scope) can be found in relevant Annexes “A”.

5 ACCREDITATION FIELD OF A LABORATORY AND PT PROVIDER

A calibration laboratory defines its “Accreditation field” based on activities defined „Performance specification” (see article 4) by a general description in the fields of what quantities is the calibration performed of relevant measuring instrument and/or reference materials and / or perform expert measurement of the measurement of physical quantities. If a laboratory is proficient in calibration certificates or other form of presentation of results to give opinions and interpretations as an accredited activity, it should be mentioned in the “Accreditation field”. Examples of defined “Accreditation fields” can be found in the Annex „B“.

A testing laboratory defines its “Accreditation field” based on activities defined in „Performance specification” (see article 4) by a general description what methods or procedures for testing of relevant materials are used or what methods or procedures are used for measurement. If a laboratory is competent also to carry out sampling and/or to give opinions and interpretations in test protocols or other form of presentation of results (it also applies to medical laboratories meeting the requirements of ISO/IEC 17025) as an accredited activity and/or it is a laboratory with a flexible scope, these should be mentioned in Field of Accreditation. Examples of defined Field of Accreditation can be found in the Annex „B“.

A medical laboratory defines its Field of Accreditation based on activities defined in Specification of activity (see article 4) by a general description what methods or procedures for analysis and examination of relevant biological materials taken from a human organism are used. If a laboratory is also competent in sampling/or it is a laboratory with a flexible scope, these should also be mentioned in the Field of Accreditation. Examples of defined Field of Accreditation can be found in the Annex „B".

A PT provider defines its Field of Accreditation based on activities defined in Specification of activity (see article 4) by a general description of testing sphere and/or calibration where PT are provided. Examples of defined Field of Accreditation can be found in the Annex „B".

6 TYPES OF LABORATORIES

From the point of view of accreditation scope flexibility, possibility to introduce new methods, modification of used methods and possible development of new testing and/or calibration methods, laboratories are classified in two types:

Type of laboratory with a fixed scope of accreditation:

The laboratory is authorized to use, within accredited activities, standard, validated modified standard or validated non-standard testing and/or calibration methods or sampling in a fixed scope which is not modified or validated during the validity period of accreditation.

Type of laboratory with a flexible scope of accreditation is competent:

in frames of its accredited activities routinely use the standard, validated modified standard or validated non-standard testing and/or calibration methods or sampling, it is able to modify and validate during the accreditation validity period.

The laboratory can also verify newly introduced standard methods.

When laboratory shows its competence to develop and validate new methods, it can perform this activity within the accredited activities.

Flexibility is not related to the change of the principle of methods used or defined principles for development of new methods.

In case of the laboratory with flexible scope a table "Staff members competent to modify and validate methods/develop new methods during the accreditation validity period" should be completed. In the Table individual competent laboratory workers are mentioned with whom this competency of the laboratory relates to.

The scope of accreditation of the laboratory with flexible scope is listed in the List, managed by the laboratory independently and shall be available on the web site of the laboratory or organization, of which the laboratory is part or on the request at the head of laboratory. If the List is published on the website of the organization/laboratory, access to the List shall be easy, not complicated, and SNAS shall have information on its exact address. This address shall be made public also on the SNAS web site. The changes in the List may be done by the laboratory only after having performed all required activities and after fulfilling all

requirements specified in its own documented management system of flexible scope. Laboratory is obliged to inform SNAS in writing about all made changes in the List.

7 OPINIONS AND INTERPRETATIONS

A laboratory is authorized, in report on results (test protocols or calibration certificates), to express opinions or interpretations concerning achieved results. These opinions and interpretations are related mainly to:

- opinions on statement of compliance or non-compliance of results with specified requirements;
- meeting of contract requirements;
- recommendations how to use results;
- instructions how to use results for improvement;
- intervals or conditions of results validity etc.

Statement of conformity or non-conformity of results with specified requirements, or commentary on results in medical laboratories is not considered to be expression of opinion or interpretation of a result.

If a laboratory seeks to be accredited for expression of opinions and interpretations it is obliged to complete a Table "Staff members competent to express opinions and interpretations". In the table individual competent staff members are mentioned. In the tables „Performance specification" should be marked what activity results the expression of opinions and interpretations will be related to (see individual Annexes "A"). The competence to express opinions and interpretations is an additional activity connected to the laboratory performance which is a subject of accreditation.

In medical laboratories, expressing opinions and interpretations is an integral part of the results presentation.

8 IN-HOME/IN-HOUSE CALIBRATION

If a laboratory does not use a competent external provider of this service for calibration of its measuring instruments and/or reference materials it is authorized to ask SNAS to consider the laboratory competence to perform such type of calibration for its own use (e. g. in the field of calibration of measurement glass, photometers, own standard materials etc.).

Performance of calibrations directly connected with testing methods (identification of response depending on the content of the monitored parameter/intensity of parameter), e. g. in the field of photometric or separation tests, is not considered to be an "in-home" calibration, but it is an integral part of the used method. Neither, adjustment of measuring instrument and its inspection are considered to be in-home calibration.

If a laboratory seeks to be reviewed for “in-home” calibration it is obliged to mention this fact in the Annex to the application for given accreditation field in the respective text fields in AIS.

If a laboratory performs "in-home" calibration and this will not be included in the application for the accreditation service, the activity can not be assessed, which may lead to problems with ensuring of acceptable performance of calibration and thus the failure to comply with the accreditation requirements to ensure traceability of test results.

Note: Calibration of measuring instruments carried for the need of calibration laboratory is not considered in-home calibration if the calibration range coincides with the scope of accreditation calibration laboratory.

9 ANNEXES

ANNEX A1 (informative) - Guidelines for calibration laboratories

ANNEX A2 (informative) - Guidelines for testing laboratories

ANNEX A3 (informative) - Guidelines for medical laboratories

ANNEX A4 (informative) - Guidelines for proficiency testing providers

ANNEX B (informative) - Scope of accreditation

ANNEX A1 – GUIDELINES FOR CALIBRATION LABORATORIES

In general

Form of activities specification for calibration laboratories seeking accreditation is given in the following tables which are annexed to the Application for Accreditation, Application for Accreditation is filled in by the applicant in the AIS. By filling in relevant text fields the applicant specifies activity which he seeks accreditation for and which will be, after the completing accreditation, re-accreditation, accreditation extension or after making changes, mentioned in the Annex to the accreditation certificate. The laboratory will add these activities in the List in case of accredited flexible scope.

All types of laboratories fill in the relevant text fields in AIS. When the laboratory with flexible scope performs part of activities as laboratory with fixed scope the table A1-1 is to be filled in independently for activities carried out as routine activities (fixed scope) and activities covered by the flexible scope. Table A1-1 for laboratory with flexible scope will be a base for a List of activities controlled by the laboratory only.

If a laboratory apart from calibration, performs also other activities of conformity assessment that should be accredited (measuring, testing of measuring instruments, etc.) it shall elaborate for each activity the specification in accordance with the relevant model table (Table A1-1 serves exclusively for the specification of accreditation scope of calibration laboratory).
If calibration laboratory simultaneously performs the measurement of quantity with instruments which calibrates, the scope of such activities is included in activity of calibration laboratory.
Table A1-1k is used for specify the scope of accreditation calibration laboratory (calibration activity), Table A1-m is used for specify the scope of accreditation calibration laboratory, which performs measurement of quantities.
If a laboratory performs measurements of other variables, which has not in its scope of calibration and with measuring instruments that have been calibrated in other calibration laboratory, such measurements is considered the test activity. Then be completed the Table A2-1.
If a laboratory seeks accreditation for expressing opinions and interpretations it shall fill the Table A1-2.

If a laboratory seeks accreditation for performance of modifications and validations of used calibration methods, it shall complete the Table A1-3.

Calibration laboratory performing its own (in-home) calibration filled in relevant text files in AIS .

Laboratories do not fill tables which are not relevant for the accreditation.

Example of tables for activities specification/accreditation scope of a calibration laboratory:

Table A1-1k

Specification of activities for calibration laboratory

Item	Kind of measuring instrument/ measurement means	Measurement range	Expanded uncertainty *U* (*k*=…)	Established methods		Other specifications
				Kind/ Principle	Identification	
1	2	3	4	5	6	7

Table A1-1m

Specification of activities for calibration laboratory performing measurements

Item	Measured quantity	Measurement range	Expanded uncertainty *U* (*k*=…)	Established methods		Other specifications
				Kind/ Principle	Identification	
1	2	3	4	5	6	7

Instructions for filling the table:

Column 1:
In the vertical field "Item" by order number listed are items to which the specification is divided. The purpose of arranging into numbered items is to ensure limpidity of specification and to simplify reference to table in various circumstances (e.g. during the planning of assessment, etc.) If a laboratory calibrates measuring instruments of several quantities it is recommended to make basic division (1., 2.,…) according to quantities and more detailed division (1.1, 1.2, 1.3….) according to the kind of measuring instruments (tick measuring instruments for length, gauge blocks, dial pointer electrical measuring instruments, digital electrical measuring instruments etc.).

Column 2:
Table A1-1k: In the column 2 listed are kinds of measuring instruments/measuring means which have common characteristic signs, at least those for which related are data given in other columns. In principle, breakdown into types can be made (for. example length measures can be itemized down to measures, gauges, etc., vacuum meters can be itemized in to deformation, compress ones, Pirani, ionizing, etc., pyrometer itemized into brightness, color, total radiation, etc.) or to merge (e.g. thermo-electrical thermometers and temperature sensors, measuring

instruments for air humidity, etc.). The details of this specification depend on type of laboratory. For laboratory with fixed scope the specification shall be sufficiently detailed, covering nomenclature of types of measuring instruments for calibration of which the laboratory is competent/accredited . For laboratory with flexible scope, specifications in this column shall set types, or kinds of measuring instruments, which are related to competence/accreditation of a laboratory. The options for setting range are various, the common sign may be the used measurement method, measured quantity (DC-AC-RF electrical quantities …), medium which the quantity is bound to (water, technical liquids…) etc. It is important to choose the approach that ensures transparency of information of measuring instruments, which is laboratory capable to calibrate.
Table A1-1m: If a laboratory provided measurement, in this column will be the kind of quantity to be measured.

Column 3:
Table A1-k: In this column listed is the range of values of the measured quantity in which the laboratory is capable to calibrate measuring instruments listed in the column 2 with uncertainties and using methods listed in other columns. If the base for specification are values of measuring ranges of calibrated measuring instruments (usually for laboratories with fixed scope), it is necessary to respect the definition of the measurement range of the measuring instrument in accordance with STN 01 0115, particularly not to confuse measurement range with scale/indicator range. In case of multirange measuring instruments and with set of instruments of different ranges listed is lower limit of the lowest range and upper limit of the highest range. Analogically, with set of single value measures (gauge blocks, weights, etc.) listed as the measurement range are measures with lowest and highest nominal value.
Table A1-1m: If a laboratory provided measurement, in this column listed the measuring range.

Column 4:
Table A1-1k, Table A1-1m: In this column is expanded uncertainty with coverage factor *k*, which, in the case of normal (Gaussian) distribution equals 2 and which is achieved by laboratory at usual calibration conditions/measurements.
Usual conditions are:

- calibration of instruments listed in column 2 of the table and in range given in column 3,
- usage of measurement standards and of equipment listed in controlled laboratory documentation
- usage of established methods and documented procedures listed in column 5 of the table,
- performing calibrations/measurements in the working environment specified in controlled laboratory documentation
- realization of activities (preparation, entire measurements, evaluation) by selected technical staff in accordance with the conditions prescribed by methods of calibration or the other regulations.

The stated value of uncertainty corresponds to CMC (calibration and measurement capability – see Policy SNAS PL-34 and MSA-L/12). It is recommended to state, in the form of note to the heading or to the values in this column, circumstances having great influence to given uncertainties. The most often it concerns the type and a quality (accuracy class) of calibrated instruments and measured quantities for which the uncertainty values applies, or values influencing quantities in case of big impact upon uncertainty values listed in the table.

Laboratory has to demonstrate at the accreditation the relevant supporting materials to given uncertainties, such as methodology of calculation/evaluation, balances, estimates, justifications, etc.

Uncertainty declared in column 4 must not be value which the laboratory can achieve under special conditions and circumstances, like higher demand for time, staff, environment, etc. which does not occur in normal practice.

If the condition of normal distribution is not fulfilled there shall be used the coverage factor k which corresponds to a probability interval of approximately 95%. In this case the reason for using such coverage factor shall be stated in “Other specifications”.

For laboratories with fixed scope is given only one uncertainty value for given measurement range listed in column 3. With extensive measurement range (big nonlinear dependence of uncertainty, large measurement range) when it is not possible to assign a single uncertainty value to a whole range, it is appropriate to segment the range and for each sub-range assign a relevant value of uncertainty.

Uncertainties shall be given, most preferably, in absolute values of measured quantities rounded to 2 significant digits. If it is practical with particular instruments (constant value of uncertainty within the whole range) or it is commonly used to, relative values of uncertainties rounded to maximum 2 valid digits can be used. In justified cases the uncertainty can be indicated by an analytical formula expressing value of uncertainty with dependence on measured value, measurement range, etc.

Column 5:
Table A1-1k, Table A1-1m: In this column the kind or principle of employed method is listed with identification whether it is a standard method, modified standard method or own method. It is not sufficient to state just “comparison method”, it has to be specified in more detailed way which one of possible comparison methods it is. If documentation contains alternative options it has to be clearly stated which method the laboratory implemented and is capable to operate it.

For laboratory with fixed scope it has to be clear from the table which standard method is used for calibration of individual kind of measuring instruments. Reference of the method to the measuring instruments is fixed, optionality is excluded.

Laboratory with flexible scope shall declare in this column all methods implemented for a given calibration. Higher number of implemented methods for a given purpose is not a characteristic attribute of this type laboratory; it is a capability to distinguish properties and consequences of usage of individual methods and to make selection of the most appropriate method for the particular case. If nonstandard (not validated) generic method is listed the laboratory with flexible scope has to validate the procedure of its implementation.

Column 6:
Table A1-1k, Table A1-1m: In this column listed shall be normative documents specifying implemented methods and proving that the methods are standard or procedures of calibration are validated in case of generic methods. Documentation related to individual methods is expressed in the following way:

- in the case of standard method, stated is the identification reference of the standard or of other official regulation, for example:

  ISO XXXX
- in the case of not modified standard method transferred into internal regulation of a laboratory, given is the identification reference of the standard and under it in brackets identification reference of internal regulation, for example:

  ISO xxxx
  (IP yyy)
- in case of modified standard method or transferred method documented in the internal regulation of the laboratory, given is the identification reference of the internal regulation and under it in brackets identification of the standard or of the document from which the method is based on, for example:

  IP yyy
  (ISO xxxx; referenced publication)

  Note Instead of " referenced publication" given can be reference where the cited text can be found.

- in case of a method developed by the laboratory, given is its internal identification reference, for example:

  IP yyy

Column 7:
Table A1-1k, Table A1-1m: In this column are listed important specifications that, by their character, do not belong to previous columns, especially:

a. application sphere of calibration activities , e.g. in the cases, when technical limitations exist or operating in the regulated sector, which is reflected by references to relevant legislation or directives, etc.

   NOTE Laboratory must not discriminate clients from other reasons than technical (e.g. capacity, company interests, etc.).

b. location of calibration: in laboratory and/or on site, in the client's premises (it relates to technical equipment of laboratory),

c. calibration of working measuring instruments and/or working measurement standards,

d. calibration of measuring instrument for using it under nonstandard conditions (low or high temperatures, pressure, etc.),

e. provision of opinions and interpretations on presented calibration results.

NOTE If there is a need to include explanations and remarks to some items in the table these shall be numbered in the relevant cell and shall be put under the table. Table shall contain specification only.

Table A1–2

Employees capable to express opinions and interpretations

Name and surname, titles	Ability to express opinion or interpretation – Specification of activity item No.
1	2

Instructions for filling the table:

Column 1:
Given shall be names of persons which are capable to express opinions and interpretations.

Column 2:
Given shall be items from Tables A1–1 or A1–2 for which the particular persons are capable to express opinions and interpretations.

Table A1–3

Employees capable to modify and validate methods during the validity of the accreditation certificate

Name and Surname, titles	Ability to modify and validate methods – item number in the activities specification
1	2

Examples of filled in tables

Column 1:
Given shall be names of persons which are capable to modify and validate calibration methods during the validity of the accreditation certificate.

Column 2:
Given shall be items from Tables A1–1 or A1–2 for which the particular persons are capable to modify and validate calibration methods during the validity of the accreditation certificate.

Examples of filled in tables A1 - 1k and A1 – 1m

A1–1k Specification of activities of calibration laboratory

Example 1

Item	Kind of measuring instrument/ measurement means	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
				Kind/ Principle	Identification	
1	2	3	4	5	6	7
1	Water meters for cold and hot water	(0,2 – 40) $m^3.h^{-1}$	at Q_n 0,2 % at Q_{min} 0,39 %	Mass method with fixed start	STN 12345 (IP-20)	Medium used: cold water

Example 2

Item	Kind of measuring instrument/ measurement means	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
				Kind/ Principle	Identification	
1	2	3	4	5	6	7
1	Glass thermometers	(0 – 100) °C (100 – 200) °C (200 – 360) °C	0,15 °C 0,25 °C 0,80 °C	Comparison method at full immersion	DDD-23	Division of scale 1/10 °C

A1–1m Specification of activities calibration laboratory performing measurements

Example 1:

Item	Measured quantity	Measurement range	Expanded uncertainty U (k=...)	Established methods		Other specifications
				Kind/ Principle	Identification	
1	**2**	**3**	**4**	5	6	**7**
1	Temperature	(-10 to 400)°C	3.0 °C	Direct measuring with infrared camera	STN EN 13187 (DDD-28) ČSN ISO 18434-1 (DDD-29)	in situ

ANNEX A2 – GUIDELINE FOR TESTING LABORATORIES

In general

Form of activities specification for testing laboratories seeking accreditation is given in the following tables which are shown in Annex OA2 to the Application for accreditation. By filling relevant tables the applicant specifies activity which he seeks accreditation for and which will be, after the completing accreditation, reaccreditation, accreditation extension or after making changes, published in the Annex to the accreditation certificate. In case of accredited flexible scope the laboratory will supplement these activities in the List.

Laboratories of all types fill in the relevant text fields in AIS. In case when laboratory with flexible scope performs partially also activities as laboratory with fixed scope it shall fill in separately the Table A2-1 for activities performed on routine base (fixed scope) and separately for activities covered under flexible scope. Table A2-1 and Table A-2-2 for Laboratory with flexible scope will be the basis for the List managed only by the laboratory. Laboratory with flexible scope that is competent to develop new methods, fills Table A2-2.

If the testing laboratory performs also sampling it shall fill also Table A2–3 Specification of activities.

If a laboratory seeks accreditation for expressing opinions and interpretations it shall fill the Table A2-4.

If a laboratory seeks accreditation for the performance of modifications and validations of used testing or measuring methods or development of new testing or measuring methods during the validity period of accreditation certificate, it shall complete the Table A2-5.

Testing laboratory performing in-home calibration fill in relevant text files in AIS

Laboratories do not fill tables which are, from the point of view of their activities, irrelevant for the accreditation.

Examples of tables for activities specification/accreditation scope of a testing laboratory:

Table A2-1

Specification of activities for testing laboratory

Item	Subject of testing		Implemented method		Other specifications (range, uncertainty, purpose, modification/validation, opinion/interpretation, etc.)
	Object / Matrix / Environment	Property / Parameter / Index / Analyte	Principle / Kind / Type	Identification	
1	2	3	4	5	6

Instructions for filling the table:

Column 1:
In the vertical field "Item" by order number listed are items which the specification is divided to. The purpose of arranging into numbered items is to ensure limpidity of specification and to simplify reference to table in various circumstances (e.g. during the planning of assessment, etc.). For the purpose, it is possible to use instead of integer numbering other system, for example by using numbering with one decimal comma (1.1, 1.2 ... 2.1, 2.2, etc.) allowing course and also fine vertical division of the table. Identification or numbering of the item shall preferably relate to column 3 „Property…".

Vertical field "Subject of testing" is divided into two fields, as follows:

- Object (Matrix, Environment , System,)", hereinafter "Object", and
- "Property (Parameter, Index, Analyte)", hereinafter "Property".

Column 2:
In the column "Object" listed shall be specification of material subjects, objects, matrixes or environments, like "water", "drinking water", "working environment", "vehicles", "medical aids", etc. Specification details in the column "Object" relate to type of laboratory (fixed or flexible), and to data listed in column 3, 4 and 5, to methods implemented in the laboratory for testing particular properties/parameters, or to other specifications listed in column 6 (e.g. implemented method for determination of the particular element can be suitable only for fish or other types of meat or for foodstuff in general; in column 2 it is necessary to list relevant material object or environment). If the object of testing is repeated in multiple items, it is practical to list these items consecutively and to merge them.

Explanation for laboratory with fixed scope:

In column 2 shall be listed exact specification of the object that is based on used testing method (at exact specification indent is not used like it is for laboratory with flexible scope), for example "Drinking water", Lorries above 3,5 tons", etc.

Explanation for laboratory with flexible scope:

Object can be identified in more general way, e.g. "Water", "Eatables", "Air environment", etc., in case the laboratory is capable to determine listed properties of all kinds of samples, i.e. for example of drinking, waste, surface and rain water, of all types of foodstuff, of working, internal or external air environment, etc.

If it determines certain property in specific matrix (specific object) only, in column "Object" with respective property it shall enter more detailed specification of the object using dash, e.g. "– drinking water", "– kitchen salt", "– lorries above 3,5 tons", etc.

Column 3:
In this column listed shall be tested properties, parameters, indexes or analytes of objects listed in column 2. In principle, it may concern more properties of the same object by using relevant methods or the certain property of more objects. In the latter case it is possible to merge the

property for more objects into one table cell in column 3. Specification deepness of tested properties (element content, e.g. of lead, content of elements group, e.g. heavy metals, etc.) relates the same way as specification of objects to particular methods listed in columns 4 and 5.

Explanation for laboratory with fixed scope:

This type laboratory specifies exactly the object of testing together with the property (for example, “lead”, “cadmium”, “tensile strength”, etc.).

Explanation for laboratory with flexible scope:

This type laboratory shall list in observed, tested or determined property also group name of similar properties, for example “heavy metals", “pesticides”, etc., and under this title given shall be using informative properties the laboratory already tests under the dash, for example “– lead”, “–DDT”, etc. In the case that larger number of properties, tested by the laboratory, are to be reported within the group name of similar properties, these properties can be listed in note below the table. Specification of other properties in the group shall be added only after demonstrating necessary steps specified in the documented management system of flexible laboratory scope.

Vertical field “Implemented method” is divided into two cells “Principle/Kind/Type” and “Identification”.

Column 4
In this column is listed the kind or principle of used testing method. Specification of the kind shall be sufficient for distinguishing from other kinds of methods used for a given purpose (for example, for chemical testing gravimetry, titration, voltamperemetry, spectrophotometry, GC/MS, F-AAS etc.; for microbiological testing that one be cultivation, microscopy, etc.; X-ray spectroscopy for nondestructive testing of materials, etc., based on list of determining data). In case, the kind of methods is the same in more items in consecutive cells, they can be merged into a common cell.

If qualitative methods are used, entered under kind/principle of a method shall be in brackets “(qualitative test)” or similar identification.

Column 5:
In this column shall be given identifications of used methods with indication whether it is a standard method, modified standard method or own method, as follows:

- in case of standard method specified in the standard, and the AB does not have an internal working procedure to perform the test because it works exactly according to the standard the identification reference of the standard or of other official regulation shall be stated, for example:

  ISO xxxx

- in case of not modified standard method transferred into internal regulative of a laboratory, given is the identification reference of the standard and under it, in brackets, identification reference of internal regulation, for example:

ISO xxxx
(IP yyy)

- in case of modified standard method or transferred method documented in internal regulation of the laboratory, given is the identification reference of the internal regulation and under it, in brackets, identification of the standard or of the document from which the method is passed on, for example:

  IP yyy
  (ISO xxxx; referenced publication)

  NOTE: Instead of "referenced publication" given can be reference to the location where the cited text can be found.

- in case of a method developed by the laboratory, given is only its internal identification reference, for example:

  IP yyy

If the laboratory uses for determination of the particular property more standards/regulations/procedures, in column 5 given shall be only basic regulation(s) or basic standard(s) and other related regulations/standards should be listed (if needed) in column 6 "Other specifications".

Column 6:
In this column listed are important specifications that, by their character, do not belong to previous columns, especially:

a. range of measurement/results of tests if this is important from the point of information for clients or in order to limit clearly the scope of accreditation (e.g. if the laboratory is not capable to perform testing or measurements in full range specified in standard/regulation used for testing, if the legislation requires so, etc.),

NOTE: With physical quantities it is necessary to use names, symbols and units in accordance with ISO 80000. The accuracy of the listed range depends on circumstances for which that range is defined.
Range may be divided into more intervals in connection, for example, with assigned uncertainty and these intervals can overlap as regards informative values. When specifying the range, it is necessary to take care especially to the lower limit by which, usually, cannot be "zero" (lowest point of the scale in used instrument), but for example suitably expressed limit of proof or of determination.

b. expanded uncertainty of results from measurements/testing if this is important from the point of information for a client or in order to clearly limit scope of accreditation.

NOTE: Values of uncertainties in this column relates directly to listed ranges. Given shall be extended uncertainty with coverage coefficient k=2 (double of combined standard uncertainty) which the laboratory achieves on usual terms of testing, and which for the given interval of listed range represents the highest value. Uncertainties shall be given preferably in absolute values of the measured quantities rounded into two valid digits. If it is applicable for particular tested properties (constant value of uncertainty for the whole range) and commonly used too, it is possible to use also relative values of uncertainty or other suitable way. If another type of uncertainty than above is used, given shall be an explanatory notes to it or to relevant part of the table.

c. information whether for particular results of testing/measurement in reports will be given opinions and interpretations,

d. sphere for which results from testing are intended/suitable when technical limitations exist or there are specific areas in which the laboratory wants to operate, for example "Defense-related products or significant non-military material", testing for purposes of the population health safety, or the references to relevant legislation or directives, etc.

NOTE: Laboratory must not discriminate clients form other (e.g. capacity, company interests) reasons than technical ones.

e. Location of testing, if important: in laboratory and/or on site in the client's premises, etc. (it relates to technical equipment of laboratory),

f. Specific conditions under which the testing can be performed (low or high temperature, high relative humidity, etc.).

g. Characteristics of the method, if important, like limit of proof or limit of determination.

h. Other regulations related to execute test that are not listed in previous columns (eg object standards that do not include test methods but relate to test performance and evaluation of measured results).

i. Other relevant information in order to complete the complexity of information given in particular horizontal cell.

j. Reference to laws and decrees, if necessary for the regulator

NOTE: If there is a need to add explanation or remarks to any of the items in the table they shall be numbered in the relevant cell and shall be put under the table. The table shall contain only the specifications.

Table A2–2

Specification of activities of testing laboratory with flexible scope, competent to develop new methods

Item	Kind / Principle of developed methods	Subject of determination		Sphere of application	Other specifications
		Object/ Matrix, environment, system	**Property/** Parameter, Index, Analyte		
1	2	3	4	5	6

Instructions for filling the table:

Column 1:
Similarly as in Table A2–1.

Column 2:
In column "Kind/Principle of developed method" given is frame identification of the kind or of principle of a method, sufficient to distinguish it from methods of other kind or principles, for example, gravimetry, spectral analysis, mechanical test, etc.

Vertical cell "Subject of determination" is divided into two fields, "Object (Matrix, Environment)" and "Property (Parameter, Index, Analyte)".

Column 3:
In column "Object" listed shall be specification of objects, matrixes or environments for which the testing method is being developed, like "water", "drinking water", working environment", "vehicles", medical aids", etc. Specification can be given in more general terms.

Column 4:
In this column given shall be properties, parameters, indexes or analytes for which the testing methods are being developed. Specification can be given in more general terms.

Column 5:
Given shall be specification of spheres where expected is or intended for is the application of developed method, for example "agriculture", "nondestructive testing", "metallurgy", etc.

Column 6:
In this column according to needs given shall be other relevant specifications concerning e.g. validation of developed methods, assumed standardization (inclusion to an existing or under the preparation technical standard), etc.

NOTE: In case of need for explanation or for remarks to add to any of the item in the table they shall be numbered in the relevant cell and shall be put under the table. The table shall contain the specification only.

Table A2–3

Specification of activities at which the laboratory executes taking samples

Item	Subject			Method		Other specifications
	Object	Property	Place of sampling	Kind / Principle	Identification	
1	2	3	4	5	6	7

Specification in this field of testing laboratory activities shall be filled in only by laboratory performing, besides testing, also taking samples, as well as laboratory executing taking samples only.

Instructions for filling in the table:

Column 1:
Similarly like with table A2-1.

Vertical field “Subject” is divided into three cells, “Object” and “Property” and “Place of sampling”.

Column 2:
In column “Object” is given specification of objects, matrixes or environments from which samples are being taken, like “air environment”, “waste gasses”, “soils”, etc. Details of specification relates to the particular type of laboratory, to the implemented methods of sampling and to other specifications listed in column 7 of the table. For more information see guide for filling table A2-1 (column 2).

Column 3:
In this column listed shall be properties, parameters, indexes or analytes which shall be tested in taken samples. Specification deepness of tested properties depends on the same factors as in the previous column “Object”.
If the specification relates to tests already listed in Table A2–1, it is sufficient to enter the number of item from that table, under which listed are properties for which the sampling is performed (e.g. property in Scope of accreditation/ Specification of testing laboratory activities listed under No. 1-12).

Column 4:
Specified are places of sampling, like “working environment”, “down pipe”, "stationary source of pollution, "the manufacturing of concrete", "storage of aggregates", “foodstuff shops”, etc.
Vertical field “Method” is divided into two cells “Kind/Principle” and “Identification”.

Column 5:
In this column listed shall be kind and principle of used sampling method. Specification of the kind can be given as frame one, sufficient for distinguishing from other kinds of methods used for a given purpose (for example, spot sampling, poured sample, manual sampling, sampling to the filter, sampling to solution, sampling from the bore etc.). Specification of this part of the table should be identical with information specified in used standard or other sampling method.

Column 6:
In this column given shall be identifications of used methods with indication whether it is a standard method, modified standard method or own method using principles given in guide for filling Table A2–1 (column 5).

Column 7:
In this column listed are important specifications that, by their character, do not belong to previous columns, especially:

a. Information about subcontractors performing testing of taken samples.

NOTE: Subcontractors have to comply with requirements of current standard ISO/IEC 17025.

b. Indication whether in test reports will be given opinions and interpretations for sampling and related results.

c. Sphere for which the sampling is performed.

d Specific conditions under which the sampling can be executed (low or high temperatures, high relative humidity, wind speed, etc.)

e. Other regulations related to execution of sampling that are not listed in previous columns.

f. Other relevant information for completing the complexity of date in the given horizontal cell.

NOTE: In case of need for explanation or for remarks to add to any of the item in the table they shall be numbered in the relevant cell and shall be put under the table. The table shall contain the specification only.

Table A2–4

Employees competent to express opinions and interpretations

Name and surname, titles	Ability to express opinions or interpretations – Specification of activity item No.
1	2

Instruction for filling in the table:

Column 1:
Given shall be names of persons which are competent to express opinions and interpretations.

Column 2:
Given shall be items from Tables A2–1 or A2–3 for which the particular persons are capable to express opinions and interpretations.

Table A2–5

Employees capable to modify and to validate methods during the validity of the accreditation certificate

Name and Surname, titles	Ability to modify and validate methods – item number in the activities specification
1	2

Instructions for filling the table:

Column 1:
Given shall be names of persons which are capable to modify and validate testing methods during the validity of the accreditation certificate.

Column 2:
Given shall be items from Tables A2–1, A2-2 or A2–3 for which the particular person is capable to modify and validate testing methods during the validity of the accreditation certificate.

Examples of filled in tables
Table A2–1 Activities specification of testing laboratory

Item	Subject of testing		Implemented method		Other specifications (range, uncertainty, purpose, modification/validation, opinion/interpretation, etc.)
	Object / Matrix / Environment	Property / Parameter / Index / Analyte	Principle / Kind / Type	Identification	
Example 1: fix scope of accreditation					
1	Drinking water	Number of fecal streptococcus	Cultivation (quantitative)	STN ISO 7899-2	-
2	Disinfections solvents	Efficiency of disinfecting solvents	Cultivation (qualitative)	AHEM [1] Annex 7/92	N/I [2]
3	Food	Content of heavy metals - lead - cadmium	AAS - GTA[3]	IP 65/2 [4]	LOD [5] = 0,01 mg/kg; LOD = 0,002 mg/kg;
Example 2: fix scope of accreditation					
1	Waste gasses	Nitrogen oxides expressed as NO_2	Chemilumi-nescency	EN 14792 (SOP-26) [7]	Range: Uncertainty: $U_{(k=2)}$ (7 - 200) $mg.m^{-3}$ 6,7 $mg.m^{-3}$ (201 - 1000) $mg.m^{-3}$ 9,5 $mg.m^{-3}$ Sampling is an integral part of a method. Measurements are performed for official and also for technological purpose.
Example 3: fix scope of accreditation					
1	Vehicles	Fuel consumption	Flow measurement	ECC No.84 STN 30 0510	Approval of technical roadworthy of vehicles
Example 4: flexible scope of accreditation					
1	Waters: -drinking water -ground water -waste water	Number of fecal streptococcus	Cultivation (quantitative)	STN ISO 12345 STN EN ISO 65789 STN EN 12786	N/I

Item	Subject of testing		Implemented method		Other specifications (range, uncertainty, purpose, modification/validation, opinion/interpretation, etc.)
	Object / Matrix / Environment	Property / Parameter / Index / Analyte	Principle / Kind / Type	Identification	
2	Food: - Meat and meat products	Content of heavy metal: -lead -kadmium	AAS-GTA	IP 65/2 [4] (STN EN ISO 76986	

Legend:
1 - AHEM - Acta hygienica epidemiologica et microbiologica
2 - N/I – expression of opinions and interpretations
3 - AAS-GTA – atomic absorption spectrophotometry with thermic atomization
4 - IP - internal regulation
5 - LOD –limit of detection
6 - SOP - standard operating procedure

Table A2-2 Specification of activities of testing laboratory with flexible scope, competent to develop new methods

Item	Kind / Principle of developed methods	Subject of determination		Sphere of application	Other specifications
		Object/ Matrix, Environment, System	Property/ Parameter, Index, Analyte		
Example 1:					
1	Immunochemical (Western blot)	Pathological prion protein	TSE diagnostics	Food industry, Healthcare	-

Table A2-3 **Specification of activities at which the laboratory performs sampling**

Item	Subject			Method		Other specifications
	Object	Property	Place of sampling	Kind / Principle	Identification	
Example 1:						
1	Working air environment	Solid aerosol	Working environment	Membrane filters sampling	EPA 235/01 (IP 123/5)	Regulation of Min. of Health No. 25/02
Example 2:						

Item	Subject			Method		Other specifications
	Object	Property	Place of sampling	Kind / Principle	Identification	
1	Water and related matrix - underground water	Properties specified in the accreditation scope of the testing laboratory listed under No. x-z and sampling performed for the customer, the subcontractor	Wells, springs, salients, drill holes	Spot, integral sample	NRL/VŠ-ŠOP/1[2] STN EN ISO 5667-1 STN EN ISO 5667-3 STN EN ISO 19 458 STN ISO 5667-11 STN ISO 5667-18	
	- drinking water		Tap, filter plant, distribution network		NRL/VŠ-ŠOP/1 STN EN ISO 5667-1 STN EN ISO 5667-3 STN ISO 5667-5 STN ISO 5667-11 STN EN ISO 19 458	
2	Mud		ČOV[1]	Spot sample Decree No. 315/2005 Coll.	IP č.13 STN EN ISO 5667-13 STN ISO 5667-15	

Legend:
1 - ČOV – waste water cleaner
2 - NRL/VŠ-ŠOP – internal reference identification of the regulation…

ANNEX A3 - GUIDELINE FOR MEDICAL LABORATORIES

In general

Form of activities specification for medical laboratories seeking accreditation is given in the following tables. By filling relevant Tables the applicant specifies activities which he seeks accreditation for and which will be after the completing accreditation, reaccreditation, extension of accreditation or after making changes, published in the Annex to the accreditation certificate. In case of accredited flexible scope the laboratory will add these activities in the List.

Laboratories of all types fill in Table A3-1 and the laboratory with flexible scope competent to develop new methods completes also Table A3-2. Further explanation for completing tables is specified in Annex A2 in the guideline for completing Table A2-1. In case when laboratory with flexible scope performs partially also activities as laboratory with fixed scope , it will fill in separately the Table A3-1 for activities performed on routine base (fixed scope) and separately for activities covered under flexible scope. Table A3-1 and Table A3-2 for laboratory with flexible scope will be the basis for the List managed only by the laboratory.

In cases when medical laboratory carries out sampling it completes the table of the specification of activities A3-3.

If the laboratory wishes to be accredited for expressing opinions and interpretations it completes the Table A3-4 (only in the case of assessing the fulfillment of requirements of ISO/IEC 17025).

The laboratory fills in the Table A3-5 in case it wishes to be accredited for the performance of modifications and validations of established testing methods/development of new testing methods or measurements during the validity of accreditation certificate.

Medical laboratories performing own (in-home) calibration proceed according to part 8 of this MSA.

Laboratories do not complete those tables which are irrelevant in terms of their activities for accreditation.

Examples of tables for activities specification/accreditation scope of a medical laboratory:

Table A3-1

Specification of activities for medical laboratory

Item	Object of test		Established method		Other specification (range, uncertainty, purpose, equipment, etc.)
	System / Biological material	Indicator/ Analyte/ Parameter	Principle / Kind / Type	Identification of a method	
1	2	3	4	5	6

Instructions for filling the table:

Column 1:
In the vertical field „Item“ the order number is used for items which the specification is classified into. The purpose of arranging into numbered items is to ensure transparency of the specification and simplify references to the table in different connections (e.g. evaluating the range and complexity related to assessment, assigning tasks to assessors, indicating discovered defects, etc.).
As long as it is meaningful it is possible replace consecutive numbers by other way for example by using numbering with one decimal point (1.1, 1.2, ... 2.1, 2.2, etc.) which enables rough and soft vertical classification of the table. The indication or numbering of an item should preferably relate to the column 3 „Analyte/Indicator/Parameter“.

The vertical field „Object of test“ is divided into two fields – „System/Biological material“ and „Analyte/Indicator/Parameter“.

Column 2:
In the column „System/Biological material“ a matrix is mentioned for example „blood“, „serum“, „urine“, etc. If the system or biological material repeats in several items it is meaningful to mention one under another and unify.

Column 3:
Analyzed indicators are specified in this column. Basically, it can be a determination of several properties of the same matrix by using respective method or concrete property of different matrices. In the second case in column 3 it is possible to merge more indicators into one field of the table.

The vertical field „Applied method“ is divided into two fields – „Principle/Kind/Type“ and „Indication“

Column 4:
In this column the kind and principle of applied method of determining respective indicator is mentioned. It shallt be defined the kind of a method in a way that the differentiation of method from other kinds of used methods for given purpose (e.g. spectrophotometry, potentiometry, cultivation, etc.) will be possible. If the kind of the method is the same in the cells followed one under another it is possible to merge relevant rows into common field.

When using qualitative method „(qualitative method/examination)“ or similar mark is written in brackets under the kind/principle of the method.

Column 5:
In this column should be given identification of a method used with specifying whether it is a standard method, modified standard method or its own method and that in the way specified in the instructions for completing Table A2-1, column 5.

In case the laboratory uses several methods for determining relevant property, in column 5 the basic guideline (basic guidelines) or norm (norms) are specified and in case of need the rest is marked in column 6 „Other specifications“.

Column 6:
In this column important specifications are mentioned which with their character do not belong to previous columns. In the case of medical laboratories assessed to meet the requirements of ISO 15189 it is not required to indicate giving the opinions and interpretations.

Table A3-2

Specification of activities for medical laboratory with flexible scope competent to develop new methods

Item	Kind / Principle of developed methods	Object referred to		Application field	Other specification
		Biological material / System	Indicator / Parameter, Analyte		
1	2	3	4	5	6

Instructions for filling the table:

Column 1:
Similarly as to the Table A3-1.

Column 2:
In the column „Kind/Principle of developed methods“ a informative identification of the kind or the principle of the method sufficient for differentiation from other kinds or principles of methods like photometry, spectrum analysis, electrochemistry, etc. are mentioned.

Vertical field „Object referred to“ is divided into two fields – „Biological material/System“ and „Indicator/Parameter, Analyte“.

Column 3:
In the column „Biological material/System“ a specification matrix for which the method is developed, for example „blood“, „serum“, „urine“, etc. is mentioned. The specification can be more general.

Column 4:
In this column indicators or analytes for which the methods of testing in column 2 of given matrices are developed, are mentioned. The specification can be more general.

Column 5:
A specification where usage of developed method is assumed or determined like „biochemistry“, „hematology“, etc. is mentioned.

Column 6:
In this column other actual specifications concerning for example validation of developed methods, assumed standardization, etc. are mentioned if need.

Note: If it is needed to put explanations or notes to some items of the table they shall be marked in relevant field by order number and shall be mentioned under the Table. The Table should contain only specifications.

Table A3-3

Specification of activities which laboratories perform sampling for

Item	Object			Method		Other specifications
	Biological material/ System	Indicator/ Analyte	Place of sampling	Kind / Principle	Indication	
1	2	3	4	5	6	7

Specification in this field of activity is completed by the laboratory which besides testing performs also sampling.

Instructions for filling the table:

Column 1:
Similarly as to the Table A3-1.

Vertical field „Object“ is divided into three fields – „Biological material/System“, „Indicator/Analyte“ and „Place of sampling“.

Column 2:
In the column „System/Biological material“ the kind of taken sample from a patient, for example „blood“, „serum“, „urine“, etc. is mentioned. If the object of the testing repeats in more items it is meaningful to put these items on after another and merge them.

Column 3:
In this column analyzed indicators in column 2 of relevant sampling biological materials is mentioned. If the specification relates to examinations already specified in Table A3-1 it is sufficient to specify the item number of this table where are indicators which samples are performed for.

Column 4:
Places of sampling like „the room determined for sampling“, „ambulance of a specialist doctor“ etc. are specified.

Vertical field „Method“ is divided into two fields – „Kind/Principle“ and „Indication“.

Column 5:
In this column the kind or principle of established sampling method is mentioned. The specification of the kind of the method can be informative, sufficient for differentiation from other kinds for given purpose of established methods (e.g. „sampling from a finger usinig capillary“, “venous sampling” etc.). The specification of this part of the Table should be identical with information which is mentioned in used standard or other sampling method.

Column 6:
In this column indications of established methods with the identification whether it is a standard method, modified standard method or own method and in accordance with the principle specified in the instructions for completing the Table A2-1 (column 5) are mentioned.

Column 7:
In this column important specifications which with their character do not belong to previous columns are mentioned. Examples of specified information in the field „Other specifications“ are indicated in instructions for completing Table A2-3, column 7.

Table A3-4

(only in the case of assessing the fulfillment of requirements of ISO/IEC 17025).

Personnel competent to provide opinions and interpretations

Name and surname, title	Competency to provide opinions and interpretations - - item in the activities specification no.
1	2

Instructions for filling the table:

Column 1:
Names of persons who are competent to provide opinions and interpretations are specified.

Column 2:
Items from Tables A3-1 or A3-3 for which relevant persons competent to provide opinions and interpretations are specified.

Table A3-5

Personnel competent to modify and validate methods during the validity of the accreditation certificate

Name and surname, title	Competency to modify and validate methods - - item in the activities specification no.
1	2

Instructions for filling the table:

Column 1:
Names of persons who are competent to modify and validate testing methods during the validity of the accreditation certificate are specified.

Column 2:
Items from Tables A2-1 or A2-3 for which respective persons competent to modify and validate testing methods during the validity of the accreditation certificate are specified.

Examples of completed tables

A3-1 Specification of activities for medical laboratory

Item	Object of test		Applied method		Other specification (range, uncertainty, purpose, equipment, etc.)
	System / Biological material	Indicator/ Analyte/ Parameter	Principle / Kind / Type	Indication	
Example 1: fix scope of accredotation					
1	serum	Albumin	Photometry	PL-albumin Biovendor	-
2		Alkaline phosphates			-
3		Amylase			-

Annotation:
1 - ŠPP – standard working procedure

A3-2 Specification of activities for medical laboratory with flexible scope competent to develop new methods

Item	Kind / Principle of developed methods	Object referred to		Application field	Other specifications
		Biological material / System	Indicator / Parameter, Analyte		
1	Spectrophotometry	Biological materials taken from human body	Biochemical indicators	Biochemical analysis	Validation and standardization of developed methods

A3-3 Specification of activities for which laboratory performs sampling

Item	Object			Method		Other specifications
	Biological material/ System	Indicator/ Analyte	Place of sampling	Kind / Principle	Indication	
1	Capillary blood	Glucose	Reception room - sampling	Blood sampling from a finger capillary	Operating manual Super GL (ŠPP no.21)	-
2		Erythrocytes			Operators manual Sysmex K1000 (ŠPP no.35)	-

Annotation:
1 - ŠPP – standard working procedure

ANNEX A4 – GUIDELINE FOR PROFICIENCY TESTING PROVIDERS

In general
Specification of the PT provider activities are specific. It will be considered as flexible specification of activity, where the „Field“ and „Subject of proficiency testing” represent the scope of accreditation. The informations of compared properties**,** parameters, etc. for given item of test are only informative. Form of activities specification for providers of interlaboratory proficiency testing and of interlaboratory comparisons is given in the following table A4–1. By filling the table the applicant specifies activity which he seeks accreditation for and which will be, after the completing accreditation or its extension mentioned in the Annex to the accreditation certificate.

Specimen of the table for accreditation activity/scope specification of the proficiency testing provider

Table A4-1

Item	Sphere	Object of proficiency testing	Compared properties (parameters, indicators, analytes), Range of compared values (informative)	Other specification
1	2	3	4	5

Instructions for filling the table:

Column 1:
Serial number of the activity

Column 2:
In the column “Field” shall be listed such fields which are characterizing the orientation of activity of PT provider, as: living/working environment, construction materials, metrology, food, water, hematology, serology, clinical mycology, geology, safety of products, etc.

Column 3:

In the column “Subject of proficiency testing” will be listed specification of material subjects, objects, matrixes or environments, with which the proficiency testing of interlaboratory comparison shall by performed, like “water”, “working air environment”, “measuring instruments for mechanical quantities”, etc. If the object of testing is repeated in multiple items, it is practical to list these items consecutively and to merge them.

Column 4:
In this column will be listed data and information, only for informative reason of participants, as compared properties, parameters, indexes or analytes or area of application, as for example "content of elements: Cd, Pb, …", microbiological indicators: Escherichia coli ...", kind of measuring instruments of ionizaing radioation", "samling of probes", etc. Any changes of listed properties etc. are only item of updating of the scope of accreditation, if the provider ask for this. For actual selection of listed parameters in particular programs is responsible the PT provider and depends for example on his relevant subcontractor.

Column 5:
In this column „Other specification" are listed only informative piece of information for example frequency of repetition of organization of programs, or possible relation to relevant legislation, if some programs have some relation to regulatory requirements (for example verification of water meters if it is relevant) etc.

NOTE: If there is a need for explanation or for remarks to add to any of the item in the table they shall be numbered in the relevant cell and shall be put under the table. The table shall contain the specification only.

Example for filling the table

A4-1

Item	Field	Subject of proficiency testing	Compared properties, parameters, indexes or analytes Range of values compared (informative)	Other specification (informative)
example 1				
1	Geology	Geological and ecological materials (ore and non-ore materials, solid fuels, products of combustion, soils, sediments)	Content of elements: Ag, Al, As, Au, B, Ba, Bi, C, Ca, Cd, Ce, Cl, Cr, Cs, Cu, Dy, Er, Eu, Fe, Ga, Ge, Gd, Hf, Hg, In, K, La, Li, Lu, Mg, Mo, Na, Nb, Nd, Ni, P, Pr, Rb, S, Sb, Se, Si, Sn, Sr, Ta, Ti, Te, Th, Tl, U, V, W, Zn, Zr, Y, Yb, Loss by annealing, Loss by drying (0,01-1.106) mg.kg-1	Once a year

Item	Field	Subject of proficiency testing	Compared properties, parameters, indexes or analytes Range of values compared (informative)	Other specification (informative)
2	Water	Waste water	Taking samples for determination of heavy metals and polycyclic aromatic carbohydrates in full range of concentration in WW	Twice a year
Example 2				
1	Metrology	Calibration of measuring instruments of length	- End gauges until 1000 mm - linear measure until 2000 mm	once a two years
2		Calibration of of thermometers: - Liquid in glass thermometers, - resistance and semiconductor sensors	until 500 °C until 660 °C	

Legend:
1 – WW – waste water

ANNEX B – ACCREDITATION SCOPE

1. Calibration laboratories

Examples for definition of accreditation scope

... competent to perform calibration of stationary and mobile automatic emission monitoring systems in accordance with the scope of accreditation specified in the annex to the accreditation certificate.

… to perform calibration of electronic non-automatic weighing instruments of accuracy class 1, 2 and 3 …

… calibration of measurement standards for mass and weight, of piston and electromechanical pressure meters, development of methods for calibration and measurement of mass and weights, of piston and electromechanical pressure meters in accordance with the scope of accreditation specified in the annex to the certificate.

Note:
When the laboratory is accredited with fixed and also flexible scope, the scope of accreditation shall be defined separately for each type.

2. Testing laboratories

Examples for definition of accreditation scope

… laboratory is competent to perform chemical, microbiological, genetic, biological and ecotoxicological testing of water, eatables, commodities for general use, cosmetics, air environment and biological materials, taking samples of water and air environment, measurement of physical quantities in living and working environment components, to express opinions and interpretations of test results in accordance with the accreditation scope specified in the annex to the certificate.

… qualitative and quantitative analysis of genetically modified organisms in eatables using molecular-biological methods…

… testing of construction products and of selected types of machines and equipment for civil engineering in accordance with the accreditation scope specified in the annex to the accreditation certificate.

… testing house is competent to perform noise measurement, dimensions, mass, breaking parameters, speed, fuel consumption, smoke and sights from the vehicles, strength of the bus adds-on, endurance strength of connecting equipment and completeness of type test in the field of car industry and of transport in accordance with EC Directives, EEC regulations and with Slovak Technical Standards.

… to perform sampling from working environment in accordance with the accreditation scope specified in the annex to the certificate.

Note:
When the laboratory is accredited with fixed and also flexible scope, the scope of accreditation shall be defined separately for each type.

3. Medical laboratories

3.1 Field of activities of medical laboratories

* clinical chemistry
* clinical biochemistry
* clinical microbiology (bacteriology, parasitology, mycology)
* clinical virology
* clinical hematology and transfusiology
* clinical immunology and allergiology
* medical genetics
* clinical pathology
* clinical toxicology and pharmacology

3. 2 Examples for definition of accreditation scope

… laboratory is competent to conduct clinical biochemical, immunological and hematological examinations using physical-chemical and immunological methods in the blood serum, urine, capillary and venous blood in accordance with the accreditation scope specified in the annex to the accreditation certificate.

… development and research of immunological, immunohistochemical and molecular-biological methods for diagnosis of prion diseases, slow neural infections and for identification enteral viruses, as well as performance of bacteriological, virological, immunological, biochemical and molecular biological methods for fagotype of salmonella, characterization and preservation of microorganism cultures, for sterilization processes control and control of destruction of biological material, for proving presence of HIV/Aids viruses and antibodies against them, for proof of presence and visualization of prion diseases in accordance with the accreditation scope specified in the annex to the certificate.

Note:
When the laboratory is accredited with fixed and also flexible scope, the scope of accreditation shall be defined separately for each type.

4. Proficiency testing providers

Examples for definition of accreditation scope

… competent to organize proficiency testing/interlaboratory comparisons in the field of physical-chemical, microbiological and hydrobiological, ecotoxicological, radiochemical testing and special organic and inorganic analysis of water and in the field of sampling water.

… competent to organize proficiency testing schemes for objects of calibration of measuring for geometrical, mechanical, thermo technical, frequency and time, calibration of reference materials and quantities of ionizing radiation in accordance with the accreditation scope specified in the annex to the certificate.

… competent to organize programmes of proficiency testing/interlaboratory comparisons in the field of waste analysis and their lixivium in accordance with the accreditation scope specified in the annex to the accreditation certificate.

***