SNAS SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

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

MSA–L/01

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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 AND TERMS USED

2.1 ABBREVIATIONS

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

2.2 TERMS

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

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 DOCUMENTS

ISO/IEC 17000 Conformity assessment. Vocabulary and general principles.
ISO/IEC 17011 Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
Standards of ISO 80000 series - from part 1 to part 14: Quantities and Units.
ILAC-P14 ILAC Policy for Uncertainty in Calibration
ILAC-G18 Guidelines for the formulation of Scopes of accreditation for Laboratories.
EA-2/15 M EA Requirements for the Accreditation of Flexible Scopes (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 Uncertainty of Measurement in Calibration. (MSA-L/12 Vyjadrovanie neistôt merania pri kalibrácii.)
EA-4/17 M 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 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,. 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. If a laboratory is proficient in calibration certificates or other form of presentation of results to give opinions and interpretations 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“.

The scope of accreditation of calibration laboratories must not include items for measurement of physical quantities. The measurement of physical quantities must be specified in the scope of accreditation for testing laboratories. The transitional period for the implementation of this change in the field and scope of accreditation for the calibration laboratory is until the next assessment in the CAB.

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 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, examination and/or calibration where PT are provided. Examples of defined Field of Accreditation can be found in the Annex „B“.

6 TYPES OF LABORATORIES

a.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:

6.1 FIXED SCOPE OF ACCREDITATION LABORATORY

b. The laboratory is authorized to use, within accredited activities, standard, validated modified standard or validated non-standard testing, examination and/or calibration methods or sampling in a fixed scope which is not modified or validated during the validity period of accreditation. The fixed scope does not allow additional or modified activities to be swiftly added to the scope without further assessment, even though general competence in the field has already been demonstrated. Accredited CAB can apply an extension of the scope at any time during the accreditation cycle. The assessment being carried out in real time, within the meaning of Act No 505/2009, as amended and the relevant directives.

6.2 FLEXIBLE SCOPE OF ACCREDITATION LABORATORY

The laboratory may routinely use standard, validated modified standard or validated non-standard methods of testing, investigation, calibration, sampling as a part of accredited activities and may modify and validate them during the period of validity of the accreditation.

This Chapter sets out the general requirements for a laboratory with flexible scope that allow an accredited CAB to assume responsibility for managing all scope of accreditation or part of them without the need for prior assessment by the accreditation body of any new activity. In this case, CAB shall ensure that there is generally a clear description of competence for potential customers, other stakeholders and the market, serving not only SNAS and CAB needs, but also end-users of customer-to-customer accreditation services. The requirements are based on EA-2/15 (MSA-07 and PL-21), ILAC-G 18 and EA-4/17.

6.2.1 Limitations on the flexible scope of accreditation

6.2.1.1 Outputs (Certificates, protocols, reports, etc.) issued by CAB accredited for flexible scope and CAB accredited for a fixed scope are equal and equally reliable.

6.2.1.2 SNAS has the right to decide whether or not to grant accreditation for a flexible scope to a particular CAB.

6.2.1.3 SNAS does not allow laboratories accredited for flexible scope to use flexibility within the applicable RA:

1. In calibration laboratory
   - on a new principle
   - to another area of accreditation defined by SNAS

- to a new workplace
- to a new place of work of the laboratory
- to a new area of accreditation covered by another accreditation scheme (testing, examination, inspection, certification)
- regarding CMC (uncertainity)
- regarding measurement range
- regarding method modification outside of measurement range and CMC

2. In testing laboratory
   - on a new principle
   - to another area of accreditation defined by SNAS
   - to a new workplace
   - to a new place of work of the laboratory
   - to a new area of accreditation covered by another accreditation scheme (calibration, examination, inspection, certification)
3. In medical laboratory
   - on a new principle
   - to another area of accreditation defined by SNAS
   - to a new workplace
   - to a new place of work of the laboratory
   - to a new area of accreditation covered by another accreditation scheme (testing, calibration, inspection, certification)

6.2.2 General

6.2.2.1 Flexible scope accreditation transfers more responsibility to CAB by demonstrating the way they work is correct, fit for purpose and is carried out competently, consistently and permanently.

6.2.2.2 The flexible scope reflects CAB's competence not only to professionally carry out the activities covered by accreditation, but also to the ability to manage all processes within a flexible scope and its commitment to providing accredited activities within this scope.

6.2.2.3 It is necessary for the CAB documented plan/development process to address how the organization sets entry requirements, how it develops conformity assessment services, how it verifies to meet the requirements and how it validates complying with the requirements.

6.2.2.4 Neither SNAS nor CAB in any way indicates that an accredited CAB whose scope is flexible is more competent than a CAB with a fixed scope of accreditation. The results of the accredited activities of laboratories examination, testing, calibration, measurement, etc.) and of the PT organizer SNAS consider equivalent and at the same quality level, regardless of whether they have been obtained within a fixed or flexible scope.

6.2.2.5 SNAS shall assess CAB´s extension of accreditation in flexible scope that CAB demonstrates its mode of operation is correct, fit for purpose and is carried out impartially, competently and consistently.

Where a laboratory has been granted a flexible scope of accreditation, it shall be permitted to include the activity in its scope of accreditation on the basis of its own approval without assessment by SNAS before the start of the activity. The possibility of adding new methods, modified or developed methods within a flexible scope does not include new principles for testing, calibration, measuring or examination that were not included in the previous flexible scope of accreditation.

In calibration, possibilities for flexible scopes are more limited than in testing. It is not possible to allow flexibility regarding parameters (measurands) in calibration, because different measurands require completely different techniques. It is also not possible to allow flexibility regarding measurement range and CMC (Calibration and Measurement Capability).

Degrees of freedom within the flexibility of calibration laboratories:

- Flexibility concerning subjects/instruments
  It means flexibility allowing for changes related to different subject/instrument (e.g., in electrical calibrations) and using the specified method within the described measurement range and CMC.
- Flexibility concerning the performance of a given method
  Means flexibility allowing for changes in the performance of a particular method of the method within the described measuring range and CMC

The transitional period for the implementation of these changes in the scope of flexible accreditation in calibration laboratories is until 31.12.2022.

Degrees of freedom within the flexibility of testing laboratories:

- Flexibility concerning subject/matrix/environment
  It means flexibility allowing for changes in different subjects/matrices/environments within a certain area.
- Flexibility concerning characteristics/parameters/indicators/ analytes
  Means flexibility allowing for changes in parameters
- Flexibility concerning the performance of a given method
  Means flexibility allowing for changes in the performance of a particular method for a given sample type and parameter (e.g., modification of the measurement range and its uncertainty)
- Flexibility concerning the method
  It means flexibility to introduce methods that are equivalent to those included in the flexible scope of accreditation (the basic principle of the method is maintained).

Degrees of freedom within the flexibility of medical laboratories:

- Flexibility concerning biological material/matrix
  It means flexibility allowing for changes in different biological materials/matrices within a certain area.
- Flexibility concerning analytes/parameters of analysis
  Means flexibility allowing for changes in analytes/parameters (e.g. the flexibility consists in the addition of new analytes and/or parameters inside the group. For example, addition of individual vitamins inside a group “vitamins”.)
- Flexibility concerning the performance of a given method

Means flexibility allowing for changes in the performance of a particular method for a given sample type and parameter (e.g., modification of the measurement range and its uncertainty)

- Flexibility regarding the method
  It means flexibility to introduce methods that are equivalent to those included in the flexible scope of accreditation (the basic principle of the method is maintained).
- a combination of two or more of these flexibilities.

When formulating a flexible scope, it is important that the limits of flexibility are clearly set. In any case, the laboratory shall maintain for SNAS control purposes an up-to-date list of all methods covered by accreditation, including newly modified, implemented or developed methods.

The degrees of freedom within the flexibility shall be determined by SNAS and shall be listed below the table of the flexible scope of accreditation.

6.2.2.6 Scope assessment

Competence of staff to validate modified/new methodologies

Assessment of the competence of staff at all hierarchical levels and in all positions within the laboratory is one of the key tasks of SNAS in assessing the competence of a given laboratory. The competence of laboratory staff can be obtained and demonstrated in various ways, such as:

- general knowledge of the field in which the laboratory's customers operate,
- knowledge of the risks faced by customers and the ways in which they want to use the results,
- knowledge of the procedures used and their reliability, including related uncertainties; knowledge of the various components contributing to the uncertainty of these procedures,
- education and length of experience in the field concerned,
- training received in recent years and their effectiveness,
- cooperation with scientific organizations, standardization organizations, national and international organizations contributing to the development of techniques and the application of conformity assessment procedures and their use in the field,
- internal learning processes and improvement in the form of audits, reviews and cooperation with customers.

Where a laboratory develops a new or modified method, particular attention is paid to the competence of personnel. Personnel involved in the development and modification of methods must have the necessary expertise in the methods and technologies used. They must be able to assess the suitability of the methods and the quality of the results obtained. This competence can be obtained and demonstrated in various ways, such as:

- education and training received,
- experience in the field,
- participation in research or development projects,
- work in standardization committees,
- scientific or management committees.
- successful participation in PT/ILC

- proven verifications/validations of methodologies already implemented

SNAS assesses competence for personnel authorized to develop, validate and approve methods. Where a laboratory uses a flexible scope of accreditation, the assessment shall be more comprehensive and shall include documented evidence that the laboratory operates within the flexible scope of accreditation, as well as written documents where the laboratory is taking all necessary steps in the process of developing and implementing methods within the flexible scope of accreditation.

Development and modification of the methodology
A laboratory dealing with the development and modification of methods shall ensure criteria such as:

- procedures used in the development, validation and approval of methods,
- authorization of experienced staff responsible for the development, validation and approval of new and adapted methods,
- records describing the whole process from development to approval and verification,
- management's commitment to maintain a flexible scope if accredited for this purpose.

The procedures and responsibilities for the development, implementation and validation of modified, updated or newly implemented methods shall be described in detail in the laboratory documentation. The personnel responsible shall specify the minimum quality requirements before the start of the validation and implementation process or, even better, before the whole process of developing the method begins.
For each professional field of activity of the laboratory, management must entrust an experienced staff member with overall responsibility for the modification, development and implementation of new or modified methods.

Modification and updating of development methods or activities, including any related results and other relevant data, shall be managed and kept of them. These data shall be made available to SNAS, which shall carry out their inspection at regular assessments or on request.

Responsible personnel (including quality management personnel) shall regularly review modified, revised or newly developed methods. The procedures and competences relating to the development or revision of accredited methods shall be subject to regular review by the laboratory management, taking into account the results of internal and external quality management. Records of these reviews shall be made available to SNAS.

Validation and verification
New and modified methods must be validated before being included in the scope of accreditation and the laboratory's competence to implement these methods must also be verified. As regards standardized methods, validation is not required, but verification must be carried out.

In the case of the selection of standard methods or equivalent methods within the area of application (e.g., waste testing, blood serum testing, calibration of the instrument), validation is not necessary if the use of standardized methods or their equivalents is within that subject of the standard (equivalent). However, this principle does not apply if the standard method is combined and used for a new purpose (use of the standardized method outside the area of destination). In this case, the laboratory shall validate the method.
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Documentation
Where relevant, a laboratory with a flexible scope of accreditation shall have fully documented procedures for validation of modified methods (including modification within degrees of freedom within the flexibility of selected schemes) and verification of other methods to be included in the flexible scope of accreditation and which are part of the laboratory documentation.

The suitability and robustness of these procedures is subject of assessment by SNAS before accreditation for flexible scope is granted.

The laboratory shall keep complete records of the validation and verification of additional methods and the data obtained shall be kept and made available for review in the assessment. These records are usually kept in the form of validation and/or verification reports.

Responsibility of personell
Responsible personnel shall periodically review modified, revised or newly developed methods to ensure that these methods continue to comply with explicitly defined or implicit requirements. Procedures and responsibilities relevant to the development or modification of the methods covered by accreditation shall be regularly reviewed by the responsible management in the light of the results of internal and external quality controls. Records of this activity must be available for assessment by the accreditation body.

6.2.2.7 Specific requirements for the assessment of a laboratory with a flexible scope

General requirements

Assessment activities can be divided into two practical parts that are interlinked and their complexity and relevance depend on the scope. In particular, these are:
- assessment of the quality management system;
- assessment of professional competence.

As regards the professional aspect, the assessment covers all areas of activity listed in the scope of accreditation for the entire period of validity of the accreditation. In the given area of activity, this is an assessment of selected methods within the scope of accreditation and relevant employees, carried out during the assessments. The methods selected are suitable for a credible demonstration of the laboratory's ability to perform, at the appropriate quality level, all tests, examinations, calibrations designed to the scope of accreditation.

Possible criteria for the selection of methods in terms of both quantitative and qualitative are:
- evidence of the implementation of the quality management system, experience, practice and, where appropriate, fitness for modification or development of methods,
- technical complexity,
- consequences of errors (possible risks),
- a balance between standard and nonstandard methods,
- a balance between the complete observation of the results and the control of the validation reports and/or records and/or quality management reports and/or inspection reports of laboratory equipment.

In the course of the initial assessment and reassessment, the number of methods under assessment shall be large enough to allow the methods in each area of activity to be determined and adequately assessed. At least one method must be assessed in each area of activity.

In the course of each assessment, all methods modified, newly implemented or developed by the laboratory in the period since the last assessment must be assessed.

Requirements for flexible scope
When assessing the flexible scope of accreditation, the assessment of the quality management system of a given laboratory shall focus on the implementation of validation and/or verification procedures and on the monitoring of activities related to their implementation, such as review of requirements, tenders and contracts, management review, internal audits, assessment of competence and competence of personnel, estimates of measurement uncertainty, equipment and measurement follow-up, competence testing activities and internal quality management. Particular attention must be paid to the eligibility of references to accreditation in view of the activities not yet considered within the flexible scope of accreditation.

It is also important to review the management of the List of Activities when assessing.

6.2.3 Requirements to be met by a flexible-range CAB

6.2.3.1 Cab shall maintain a "List of Activities" (hereinafter referred to as the List), which are carried out under a flexible scope.

6.2.3.2 The purpose of the List is to provide updated, transparent information on the application of a flexible scope and this must be up to date and publicly available.

6.2.3.3 CAB shall maintain and have a fully documented system for proper management of the flexible scope and its subsequent updating. Such a system must ensure that:

- responsibilities for managing a flexible scope are laid down,
- updating of the List shall be carried out only after appropriate professional activities have been carried out,
- information on what is and can be covered by accreditation is clear and exact,
- the procedure for receiving applications for activities covered by a flexible scope and which have not yet been carried out is processed and followed. Such procedures shall ensure that CAB complies with the following minimum requirements before accepting work:
    - CAB shall have access to all necessary resources and other means required to complete the specific activity required,
    - CAB has suitably qualified staff to complete the specific activity and its validation or verification,
    - responsibilities are laid down for all groups of activities,
    - the necessary validation or verification is carried out, which is determined by the CAB procedure,
    - the relevant procedure is approved,
    - the addition of further activity to the List has been validly approved by CAB management,
    - all new CAB premises that will be included in the next conformity assessment activity and have previously been notified and verified by SNAS.

    - other conformity assessment activities shall not be added to the List if they include new CAB premises which have not previously been verified by SNAS and where one or more activities are carried out.
- the contract review procedure contains elements applicable to this type of accredited scope, especially in those cases where CAB does not yet have the required activities included in the List. In such cases, the CAB must inform the client:
    - that it will not be possible to issue a report/certificate covered by accreditation, unless the activities set out in its system are satisfactorily completed,
    - that it must take note of certain facts (e.g., time needed for implementation, price, etc.).

6.2.3.4 If the validation process of the activity resulted in a conclusion that the CAB is unable to issue a protocol/certificate, the CAB must ensure that a cause analysis is carried out and adequate corrective action/action is taken. Such action shall include:

- informing the client that as long as analysis and follow-up activities are carried out, CAB will not be able to issue accredited reports/certificates and justification,
- reviewing relevant procedures or methods, where the cause would be in a specific technical problem related to the activity in question, in order to resolve the identified problem and ensure that it no longer occurs in the future,
- redefining the boundaries within the scope is flexible. In this case, CAB must inform SNAS for verifying whether the scope of accreditation has to be modified.

The current accredited flexible scope of the laboratory must be included in the List, publicly available on the website of the laboratory or organization of which the laboratory is part and at the head of the laboratory. This address will also be published on the SNAS website.

Changes to the List can only be made by the laboratory after the necessary actions have been performed and all requirements specified in its own documented flexible scope management system have been met.

The laboratory shall immediately inform SNAS in writing of any change made to the List, whereby the laboratory must submit relevant evidence of the change (eg change implementation plan, current list of activities with marked changes, validation / verification protocol) and keep a history of the changes.

The flexibility within is a laboratory accredited applies to specific laboratory personnel listed in the List of Accredited Activities and who may be modified or supplemented by laboratories. Conditions and criteria defined in the flexible scope management system of the documented CAB have to be met and accepted by SNAS. It is necessary to complete the table "Personnel competent to modify and validate methods/develop new methods during the validity of accreditation". The table shows the individual laboratory staff with whom this laboratory competence is tied.

6.2.4 SNAS approach to flexible scope

6.2.4.1 SNAS has a flexible scope accreditation policy (PL-21).

6.2.4.2 When determining the level of risks associated with activities and the applicability of a flexible scope for CAB, SNAS shall consider the following aspects during the accreditation process:

- Degree of understanding of the rules and procedures for the implementation and management of the flexible scope by CAB
- Performance and stability of the CAB management system
- Complexity of conformity activities
- Extent of flexibility provided by CAB
- Risks to the reputation of SNAS, CAB and the market
- Stability of professional staff within the CAB responsible for flexible scope activities
- CAB's knowledge and compliance with relevant standards and activities
- Stakeholders' expectations/regulatory expectations
- Planned frequency of use of flexible scope
- Scope of controls proposed by CAB to manage flexible scope
- Location and geographical risks

6.2.4.3 SNAS will check whether CAB is competent to manage a flexible scope and comply with CAB requirements. The verification process involves examining the actual examples where CAB has implemented a flexible scope. When assessing (granting accreditation, surveillance, re-accreditation) control questions for testing, calibration and medical laboratories are always completed.

6.2.4.4 In preparation, the SNAS assessment program may sample CAB activities, taking into account the risks and factors detailed in 6.2.4.2, to establish an adequate level of sampling confirming that ongoing checks (during surveillance and re-accreditation) are in place effectively in areas such as:

- All other / modified activities
- Validation
- Metrological evaluation (as appropriate) / quality assurance mechanisms
- Competence and training of personnel involved in further activities
- Availability of working instructions, legal requirements, directives, etc.
- Comparison with other activities
- Risk assessment

6.2.4.5 The scope of accreditation issued by SNAS shall include an actual reference to the List. The flexible scope of accreditation is listed as an annex to the accreditation certificate. At the next SNAS assessment, changes added within a flexible scope may be included in the accreditation certificate.

6.2.4.6 If CAB has issued accredited reports/certificates which do not comply with the requirements of this document, SNAS shall take such measures as it seems appropriate.

6.2.4.7 If SNAS finds that CAB is not complying with the requirements set out in this document, it may reconsider the scope in such a way as to reduce or even cancel flexibility, thereby limiting the specific activities listed in the List.

7 OPTIONS 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 the declaration of conformity of the 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.

The declaration of conformity of the 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-HOUSE / IN-HOME 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-house "/ „in-home" calibration, but it is an integral part of the used method. Likewise, setting the measuring instrument or checking is not considered as „in-house" / „in-home" calibration.

In the case that a laboratory wishes to be assessed for „in-house "/ „in-home" calibration, it must state this fact in an Annex to the application for the relevant area of accreditation in relevant Table in AIS. in the respective text fields in AIS.

If a laboratory performs „in-house“ / „in-home“ calibration and this will not be included in the application for the accreditation service, the activity in question will not be assessed by SNAS , which may lead to problems with ensuring of acceptable performance of calibration and thus to non-compliance 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”/”in-house” 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

9.1 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, which 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 A2-1 serves exclusively for the specification of accreditation scope of calibration laboratory).

If the laboratory requires accreditation to express opinions and interpretations it shall fill the Table A1-3.

If the laboratory seeks accreditation for performance of modifications and validations of used calibration methods, it shall complete the Table A1-2 for flexible scope of accreditation.

Calibration laboratory performing its own („in-house "/ „in-home") calibration fills in relevant text files in AIS and table A1-4.

Laboratories do not fill in those tables that are irrelevant for accreditation of their activities

Table templates for activity specification/scope of accreditation of a fixed- scope calibration laboratory:

Fill in the tables according to the laboratory specification: A1-1, A1-3, A1-4

Table A1-1

Specification of activities for calibration laboratory with a fixed scope (calibration)

Laboratory:	**with fixed scope** ☒

Item	Kind of measuring instrument/ measurement means	Calibrated / measured quantity	Measurement range	Expanded uncertainty *U* (*k*=…)	Established methods		Other specifications
					Kind/ Principle	Identification	
1	2	3	4	5	6	7	8

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:
In the column 2 listed are kinds of measuring instruments/measuring device 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.

Column 3:
In the column 3 listed is the calibrated / measured quantity by which the calibrated gauge / measuring means is calibrated or measured. A quantity is a term quantitatively describing a property or state of a physical object or effect. Physical quantities are e.g. strenght, speed, length, weight, time, electric current and temperature. Each physical quantity is assigned a unit of measure, which is listed in the "Measurement range" column.

The transitional period for the implementation of this change in the scope of accreditation for the calibration laboratory is until the next assessment in the CAB.

Column 4:
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.

Column 5:
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.
Usual conditions are:

- calibration of instruments listed in column 2 of the table and in range given in column 4,
- 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 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 apply, 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 only one uncertainty value for given measurement range listed in column 4 is given. 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 6:
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.

Column 7:
In this column normative documents specifying implemented methods shall be listed 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 8:

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

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.).

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

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

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

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 A1–3

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:
The names of the persons who are capable to express opinions and interpretations.

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

Table A1–4

Calibrations „in-house "/ „in-home "
(Calibration, metrological operations performed by its own calibration laboratory)

Calibrationse „in-house "/ „in-home " ☐ **yes** ☐ no

List of performed calibrations „in-house" / „in-home" (only in case of previous answer „yes")

Table templates for activity specification/scope of accreditation of a calibration laboratory a flexible scope of accreditation:

Fill in the tables according to the laboratory specification: A1-1, A1-2, A1-3, A1-4

Table A1-1

Specification of the activities of a calibration laboratory with flexible scope

Laboratory:	**with flexible scope** ☒

Item	**Kind of measuring instrument/ measurement means**	**Calibrated / measured quantity**	**Measurement range**	**Expanded uncertainty *U* (*k*=…)**	**Established methods**		**Other specifications**
					Kind/ Principle	**Identification**	
1	2	3	4	5	6	7	8

To mark the required scope of flexibility (in case the CAB requests a flexible scope of accreditation):

Flexibility does not apply to changing the principle of the methods, measured range and CMC used in a given flexible scope.

☐ The laboratory keeps an up-to-date list of all calibration methods with a flexible scope of accreditation on the www..... (CAB completes the link to the website)

The principle of flexibility can be used by the laboratory within the framework of:

☐ in relation to the type of measure in one type of gauge, measuring instrument, the calibration method, measured range and CMC must be maintained

☐ modification of methods included in the flexible scope of accreditation (measured range and CMC shall be preserved).

Instructions for completing table :

Column 1:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 2:
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. With a flexible scope, this column can group different types of meters within the type of meter / measuring device, while the calibration method must be maintained, but for each type of meter the measuring range and uncertainty must be defined, as well as the principle and designation of the established method.

Column 2:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 3:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 4:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 5:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 6:
Laboratory with flexible scope in this column shall declare implemented method for a given calibration, which is used for a given group of meters (individual types of meters within the type of meter). This calibration method is characteristic of several types of meters / measuring means within the type of meter, while it can be modified for individual types of meters.
Laboratory with a flexible scope have to always validate the procedure of its implementation.

Column 7:
Column is completed, as in the case of fixed scope of accreditation A1-1

Column 8:
Column is completed, as in the case of fixed scope of accreditation A1-1

Table A1-2

Personnel competent to modify and validate methods/develop new methods

First and last name, titles	Ability to modify and validate methods/develop new methods – item in in activity specification No.
1	2

Instructions for completing table A1-2:

Column 1:
The names of persons who are able to modify and validate methods / develop new methods during the validity of the accreditation shall be indicated.

Column 2:
The items from Table A1-1 for which the persons concerned are competent to modify and validate methods / develop new methods during the validity of the accreditation shall be indicated.

Table A1–3

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 and 2:
Column is completed, as in the case of fixed scope of accreditation A1-3

Table A1-4
To be filled in as for a fixed scope of accreditation.

Calibrations „in-house“ / „in-home“
(Calibrations, metrological operations performed by its own calibration laboratory)

Calibrationse „in-house“ / „in-home“ ☐ **yes** ☐ no

List of performed calibrations „in-house“ / „in-home“ (only in case of previous answer „yes“)

Examples of filled in tables A1 - 1

A1–1 Specification of activities of calibration laboratory with a fixed scope

Example 1

Item	Kind of measuring instrument/ measurement means	Calibrated / measured quantity	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
					Kind/ Principle	Identification	
1	2	3	4	5	6	7	8
1	Water meters for cold and hot water	Flowing	(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	Calibrated / measured quantity	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
					Kind/ Principle	Identification	
1	2	3	4	5	6	7	8
1	Glass thermometers	Temperature	(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

A1–1 Specification of activities of calibration laboratory with a flexible scope of accreditation

Item	Kind of measuring instrument / measurement means	Calibrated / measured quantity	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
					Kind/ Principle	Identification	
1.1	Linear length sensors	Length	(0,1 to 16) m	0,02 mm	direct comparison with a laser interferometer	SP-11-1	
	Automatic level meters	Length	(0,5 to 16) m	0,4 mm		SP-11-1 (OIML R 85)	
	Average boards	Length	do (2 000 x1 600 x 300) mm	0,005 mm		SP-11-1 (ISO 8512-1, ISO 8512-2)	
	Laser rangefinders	Length	(0 to 16) m	0,7 mm		SP-11 (ISO 16331-1:2017)	
1.2	Calipers	Length	(0 to 2 000) mm	(10 + 10 · L) µm	direct comparison with end scales	SP-11-2 (VDI/VDE/DG Q 2618)	
	Depth gauges	Length	(0 to 2 000) mm	(10 + 10 · L) µm		SP-11-2 (VDI/VDE/DG Q 2618)	
	Altimeters	Length	(0 to 2 000) mm	(10 + 10 · L) µm		SP-11-2	

Item	Kind of measuring instrument / measurement means	Calibrated / measured quantity	Measurement range	Expanded uncertainty U (k=2)	Established methods		Other specifications
					Kind/ Principle	Identification	
						(VDI/VDE/DG Q 2618)	
	Micrometers	Length	(0 to 500) mm	$(1 + 5 \cdot L)$ µm		SP-11-2 (VDI/VDE/DG Q 2618)	
	Gauges with measuring arms	Length	(0 to 1 000) mm	$(10 + 10 \cdot L)$ µm		SP-11-2 (VDI/VDE/DG Q 2618)	
1.3	Angles	Angle	α = 90°, for shoulder height up to 600 mm	3,1´´	direct comparison with altimeter	SP-5-1	
	Protractors	Angle	4 x 90°	3´	direct comparison with angular reference scales	SP-5-2 (VDI/VDE/DG Q 2618)	
	Inclinometers	Angle	2 x 90°	3´	direct comparison with angular standard scales, direct comparison with sine ruler and end scales	SP-5-2 (VDI/VDE/DG Q 2618)	
	Levels, spirit levels	Angle	do 0,5 µm/m	0,005 µm/m		SP-5-2	

Flexibility does not apply to changing the principle of the methods, measured range and CMC used in a given flexible scope.

☐ The laboratory keeps an up-to-date list of all calibration methods with a flexible scope of accreditation on the www..... (CAB completes the link to the website)

The principle of flexibility can be used by the laboratory within the framework of:

☒ in relation to the type of measure in one type of gauge, measuring instrument, the calibration method, measured range and CMC must be maintained

☐ modification of methods included in the flexible scope of accreditation (measured range and CMC shall be preserved).

9.2 ANNEX A2 – GUIDELINE FOR TESTING LABORATORIES

In general

The form of the activities specification for testing laboratories applying for 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 for which he wants to be accredited and which will be, after the completing of accreditation, re-accreditation, accreditation extension or after making changes, published in the Annex to the accreditation certificate. In the case of accredited flexible scope the laboratory will add these activities to the List.

All types of laboratories fill in the prescribed text fields in the AIS. The fixed- scope laboratory shall complete Table A2-1. Laboratory with a flexible scope shall complete Table A2-1. Table A2-1 for the laboratory with a flexible scope will be the basis for a List that will be managed only by the laboratory.

Table A2-2 shall be completed by the laboratory if it requires accreditation to carry out modifications and validations of the test or measurement methods used or the development of new methods during the validity of the accreditation.

If the laboratory requires accreditation to express opinions and interpretations, it shall complete Table A2-3.

Where sampling is also carried out by the test laboratory, it shall complete a table of activity specification A2-4.

The „in-house“ / „in-home“ calibration test laboratory shall follow Part 8 of this MSA.

The „in-house“ / „in-home“ calibration test laboratory shall fill in the relevant text fields in the AIS and Table A2-5.

Laboratories shall not complete those tables which are irrelevant to their accreditation activities.

Table templates for activity specification/scope of accreditation of a fixed- scope testing laboratory:

Fill in the tables according to the laboratory specification: A2-1, A2-3, A2-4, A2-5.

Table A2-1
Specification of the operation of the test laboratory with a fixed scope .

Laboratory:	**with fixed scope** ☒

Item	Test object		Established method		Other specifications (range, uncertainty, purpose, modification/validation, opinions/interpretations, etc.)
	Subject /Matrix /Environment	Property /Parameter /Indicator /Analyte	Principle /Type	Label	
1	2	3	4	5	6

Instructions for completing table A2-1:

Column 1:
In the vertical field 'Item', the serial number shows the items into which the specification is divided. The purpose of sorting into numbered items is to ensure the clarity of the specification and to simplify the reference to the table in different contexts (e.g. when planning an assessment, etc.). Where appropriate, another method may be used instead of integers, for example by using numbering with one decimal point (1.1, 1.2, ... 2.1, 2.2, etc.) allowing for a coarse and fine vertical breakdown of the plate.

The marking or numbering of an item shall preferably be related to column 3 'Property ...'.
The vertical field 'Test object' is divided into two fields, namely:

- 'Subject (matrix, environment, system)', hereinafter referred to as 'Subject', and
- 'Property (parameter, pointer, analyte)', hereinafter referred to as 'Property'.

Column 2:
Column 2 gives the exact specification of the subject, which is based on the test method used. The column 'Subject' shows the specification of tangible objects, objects, matrices or environments such as 'water', 'drinking water', 'working environment', 'cars', 'medical devices', etc. If the subject of the tests is repeated in several headings, it is useful to put these items behind them and merge them.

Column 3:
This column shows the characteristics tested, the parameters, the characteristics of the subjects listed in column 2. In principle, it may be the determination of several characteristics of the same object using appropriate methods or a certain characteristics of different objects. In the latter case, you can merge a property for multiple objects into a single table field in column 3. The depth of specification of the properties to be tested (element content, e.g. lead, content of a group of elements, e.g. metals, etc.) is, like the specification of objects, linked to the relevant methods set out in columns 4 and 5.
A laboratory of this type also provides an exact specification of the property (e.g. 'lead', 'cadmium', 'tensile strength', etc.) to the precise specification of the article.

The vertical field "Method in place" is divided into two fields: "Principle/Kind/Type" and "Designation".

Column 4:
This column indicates the type or principle of the test method used. The species specification shall be sufficient to distinguish from other species for the purpose of the methods used (e.g. in

chemical tests gravimetry, titration, voltamperometry, spectrophotometry, GC/MS, F-AAS, etc.; in microbiological tests, cultivation, microscopy, etc.; X-rayoscopics in non-destructive tests of materials, etc., according to the catalogue of designating data). If the kind of methods in several items is the same in the cells below each other, they can be merged into a common field.

When using qualitative methods, the type/principle of the method shall be entered in brackets '(qualitative test)' or a similar indication.

Column 5:
This column shows the designations of the methods used, identifying whether it is a standard method, a modified standard method or a custom method, as follows:

- as regards the standard method specified in the standard and the entity does not have an internal operating procedure in place to perform the test because it operates exactly according to the standard, an indication of the standard or other official regulation shall be provided, e.g.:

  ISO xxxx
- in the case of an unmodified standard method rewritten in an internal laboratory regulation, the indication of the standard shall be indicated below and below it in brackets an indication of the internal regulation, e.g.:

  ISO xxxx
  (IP yyy)
- in the case of a modified standard method or a downloaded method documented in an internal laboratory regulation, the designation of the internal regulation and below it in brackets shall indicate the standard(s) or document(s) on which the procedure is based, e.g.:

  IP yyy
  (ISO xxxx; citing literature)

  Note: the location of the "quoted literature" may be the reference where the citation is located.

- in the case of a laboratory-developed method, only its internal marking shall be provided, e.g.:

  IP yyy

Where a laboratory uses several standards/regulations/procedures to determine the relevant characteristics, only the basic regulation/basic rules or the basic standard(s) shall be indicated in column 5 and the other related rules/standards shall be entered, where appropriate, in column 6 'Other specifications'.

Column 6:
This column sets out important specifications which, by their nature, do not fall within the preceding columns, in particular:

a. a scope of measurement/test results, in so far as this is necessary for information to the customer or for a clear limitation of the scope of accreditation (e.g. if the laboratory is unable to carry out tests or measurements in full specified in the test standard/regulation used, if required by legislation, etc.)

Note: For physical quantities, names, brands and units should be used according to ISO 80000 series standards.

The accuracy of the values of the range indicated depends on the circumstances for which this range is defined.

A range can be divided into multiple intervals in relation, for example, to the assigned uncertainty, and these intervals may overlap in terms of informative values.

When indicating the range, particular attention should be paid to the lower limit, which as a rule cannot be zero (lower limit of the scale of the instrument used), but, for example, the appropriately expressed limit of proof or determination.

b. widespread uncertainty of measurement/test results, in so far as this is necessary from the point of view of information to the customer or in terms of a clear limitation of the scope of accreditation.

Note: The uncertainty values in this column are directly linked to the ranges that are listed. The extended uncertainty with a coverage factor k=2 (twice the combined standard uncertainty) achieved by the laboratory under normal test conditions and representing the highest value for the range given shall be reported. Uncertainties are given preferably in absolute values of measured quantities rounded to two valid locations. Where appropriate for the relevant test characteristics (constant uncertainty value for the whole range) and commonly used, relative uncertainty values or other appropriate means may also be used.

If a type of uncertainty other than that mentioned above is indicated, an explanatory note shall be provided for it or in the relevant part of the table.

c. information on whether opinions and interpretations will be given for the relevant test/measurement results in the protocols

d. sphere for which test results are intended/appropriate, where there are technical limitations or specific areas in which the laboratory wishes to operate, e.g. "defensee industry products or significant non-military material", testing for the purpose of protecting public health", or references to relevant legislation or directorates, etc.

Note: The laboratory must not discriminate against customers for reasons other than technical (e.g. capacity corporate interests, etc.) .

e. Place of testing, if relevant: in the laboratory and/or on site, at the customer's place, etc. (related to the technical equipment of the laboratory),

f. Specific conditions for which tests may be carried out (low or high temperatures, high relative humidity, etc.).

g. Characteristics of the method, if it is relevant, such as the limit of proof or the limit of determination.

i. Other regulations related to the test carried out which are not mentioned in the previous columns (e.g. subject standards which do not contain test methods but are related to the performance of the test and to the evaluation of the measured results).

j. Other relevant information to complement the complexity of the data in the relevant horizontal field.

k. Reference to laws and decrees in so far as this is necessary for the regulator

Note: If it is necessary to give explanatory notes or notes to certain items in the table, they shall be marked in the appropriate field with a serial number and shall be listed below the table. The table should contain only specifications.

Table A2-3

Personnel competent to express opinions and interpretations

First and last name, titles	Capacity to express opinions and interpretations - - item of activity specification No
1	2

Instructions for completing table A2-3:

Column 1:
The names of persons competent to express opinions and interpretations shall be given.

Column 2:
The entries in Tables A2-1 for which the persons concerned are competent to express opinions and interpretations shall be provided.

Table A2-4
Specification of the activities in which sampling is carried out by the laboratory

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

The specification in this area of activity of the test laboratory shall be completed by a laboratory which, in addition to testing, also carries out sampling as well as a laboratory carrying out sampling only.

Instructions for completing Table A2-4:

Column 1:
Similar to table A2-1.

The vertical field "Object" is divided into three fields, namely:
- "Subject" and
- "Property" and
- "Place of sampling".

Column 2:
The column 'Subject' shows the specification of the objects, matrices or environments from which samples are taken, such as 'air', 'waste gases', 'soils', etc. The detail of the specification shall be linked to the type of laboratory concerned, to the methods of sampling established by

the laboratory and, where appropriate, to the other specifications given in column 7 of the table. For more information, see the instructions for completing Table A2-1 (column 2).

Column 3:
This column shows the characteristics, parameters, indicators or analytes to be tested in the samples taken. The depth of specification of the properties to be tested depends on the same factors as in the previous column 'Subject'.
Where the specification relates to the tests already referred to in Table A2-1, it is sufficient to indicate the item number of this table below which the characteristics for which sampling is carried out (e.g. characteristics in the RA/activity specification referred to in No 1-12) are sufficient.

Column 4:
Sampling points such as 'working environment', 'waste pipes', 'stationary source of pollution', 'concrete plant', 'aggregate warehouse', 'food outlets', etc. shall be specified.

The vertical field "Method" is divided into two fields, namely:
- "Species/Principle" and
- "Designation".

Column 5:
This column indicates the type or principle of the sampling method used. The specification of the species is sufficient to distinguish it from other types of methods used for the purpose (e.g. point sampling, poured sample, manual sampling, filter collection, solution collection, sampling from the well, etc.). The specification of this part of the table should be consistent with the information given in the standard or other sampling method used.

Column 6:
This column indicates the methods used, identifying whether it is a standard method, a modified standard method or a custom method, in accordance with the principle set out in the instructions for completing Table A2-1 (column 5).

Column 7:
This column sets out important specifications which, by their nature, do not fall within the preceding columns, in particular:

a. Information on subcontractors conducting testing of samples taken

   Note: Subcontractors shall comply with the requirements of the current ISO/IEC 17025 standard.

b. Identification of whether opinions and interpretations will be included in the protocols for the relevant sampling and related results.

c. Sphere for which sampling is carried out.

d. Specific conditions under which sampling may be carried out (low or high temperatures, high relative humidity, wind speed, etc.).

e. Other regulations relating to sampling carried out not mentioned in the previous columns.

f. Other relevant information to complement the complexity of the data in the relevant horizontal field.

Note: If it is necessary to give explanatory notes or notes to certain items in the table, they shall be marked in the appropriate field with a serial number and shall be listed below the table. The table should contain only specifications.

Table A2-5

Calibrations „in-house“ / „in-home“
(Calibrations, metrological operations performed by its own calibration laboratory)

Calibrationse „in-house“ / „in-home“ ☐ **yes** ☐ no

List of performed calibrations „in-house“ / „in-home“ (only in case of previous answer „yes“)

Table templates for activity specification/scope of accreditation of a testing laboratory a flexible scope of accreditation:

Fill in the tables according to the laboratory specification: A2-1, A2-2, A2-3, A2-4, A2-5

Table A2-1

Specification of the activities of a testing laboratory with flexible scope

laboratory:	**with flexible scope** ☒

Item	**Object**		**Established method**		**Other specifications (range, uncertainty, purpose, modification/validation, opinions/interpretations, etc.)**
	Subject /Matrix /Environment	**Property /Parameter / Indicator/Analyte**	**Principle / Type**	**Label**	
1	2	3	4	5	6

Below the table, flexibility is clearly defined, followed by a choice of options:

Flexibility does not apply to changing the principle of the methods used in a given flexible scope.
o The laboratory maintains an up-to-date list of all test methods with a flexible scope of accreditation at www.cab.sk/flexible-accreditation/
The principle of flexibility can be used by the laboratory within the framework of:

- ☐ objects/matrices/environments
- ☐ properties/parameters/indicators/analytes
- ☐ measuring ranges and measurement uncertainties
- ☐ modifications to the methods and procedures used for testing
- ☐ identification of the methods and procedures used for testing

Instructions for completing table A2-1:

Column 2:
The subject can be marked more generally, e.g. "Water", "Foodstuffs", "Air", etc., if the laboratory is able to determine the declared properties in all types of samples, i. e.g. in drinking, waste, surface, rainwater, in all types of food, in working, indoor or outdoor air, etc.

If a certain property is specified only in a specific matrix (specific object), in the column "Object" for the relevant property it shall state a more detailed specification of the object using a bullet, e.g. "- drinking water", "- table salt", "- lorries over 3,5 t.", etc.

Column 3:
Laboratory indicate this type of monitoring, test or analyte properties group name similar characteristics, such as "heavy metals", "pesticides", etc. and below this, the properties already tested by the laboratory using an indent, such as "- lead", "- DDT", etc. shall be indicated. If a larger number of properties that the laboratory is testing is to be reported within the group name of similar properties, these properties may be listed in the labeled explanatory note below the table. The specification of other properties in the group can only be completed after performing the necessary steps specified in the documented laboratory flexible range management system.

Column 1 and 4-6 is completed, as in the case of fixed scope of accreditation A2-1.

Table A2-2

Personnel competent to modify and validate methods/develop new methods

First and last name, titles	Ability to modify and validate methods/develop new methods – item in in activity specification No.
1	2

Instructions for completing table A2-2:

Column 1:
The names of persons who are able to modify and validate methods / develop new methods during the validity of the accreditation shall be indicated.

Column 2:
The items from Table A2-1 for which the persons concerned are competent to modify and validate methods / develop new methods during the validity of the accreditation shall be indicated.

Table A2-3

Personnel competent to express opinions and interpretations

First and last name, titles	Capacity to express opinions and interpretations - - item of activity specification No
1	2

Instructions for completing table A2-3:
columns 1-2 are filled in as for the fixed scope

Table A2-4

Specification of the activities in which sampling is carried out by the laboratory

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

Below the table, flexibility is clearly defined, followed by a choice of options:
Flexibility does not apply to changing the principle of the methods used in a given flexible scope.

☐ The laboratory maintains an up-to-date list of all test methods with a flexible scope of accreditation at www.cab.sk/flexible-accreditation/

The principle of flexibility can be used by the laboratory within the framework of:

☐ objects/matrices/environments
☐ properties/parameters/indicators/analytes
☐ modifications to the methods and procedures used for sampling
☐ identification to the methods and procedures used for sampling

Instructions for completing table A2-4:
columns 1-7 are to be completed as for the fixed scope of accreditation.

Table A2-5
To be filled in as for a fixed scope of accreditation.

Calibrations „in-house“ / „in-home“
(Calibrations, metrological operations performed by its own calibration laboratory)

Calibrations „in-house“ / „in-home“ ☐ **yes** ☐ no

List of performed calibrations „in-house“ / „in-home“ (only in case of previous answer „yes“)

Examples of filling tables

A2-1 Specification of the operation of the test laboratory with fixed scope

item	Test object		Established method		Other specifications (scope, uncertainty, purpose, modification/validation, opinions/interpretations, etc.)
	Subject /Matrix /Environment	Property /Parameter /Indicator/ Analyte	Principle /Type	Label	
1	Drinking water	faecal streptococcals	Iconically (quantitative)	STN ISO 7899-2	-
2	Disinfection solutions	efficiency disinfectant. Solution	cultivary (qualitative)	AHEM [1] Annex 7/92	N/I [2]
3	foodstuff	lead cadmium	AAS-ETA [3]	IP 65/2 [4]	
4	Waste gases	Nitrogen oxides Expressed as NO_2	Chemilumi-niscencia	EN 14792 (SOP-26) [5]	Measurements shall be made for both legitimate and technological measurements
5	vehicles	consumption Fuel	measurement Flow	ECE No 84 STN 30 0510	Approval of the technical competence of vehicles

item	Test object		Established method		Other specifications (scope, uncertainty, purpose, modification/validation, opinions/interpretations, etc.)
	Subject /Matrix /Environment	Property /Parameter /Indicator/ Analyte	Principle /Type	Label	
6	LV, MV and HV Cables, conductors for LV, MV and HV overhead lines.	Electrical and thermal ageing	Resistance measurement.	STN EN 50182 STN EN 50183 STN EN 50189 STN EN 60889 STN EN 61232 STN EN 50395 STN EN 60228	DC resistance: 10 nΩ to 20 kΩ
7	Electrometers	Self - heating test.	Direct surface temperature measurement	EN 50470-1 čl. 7.2 OIML R 46 EN 62052-11 čl. 7.2 (PP-53-01)	Range: (20 až 90) °C Expanded uncertainty U (k = 2) 1 °C
8	Water – drinking, surface, waste	Temperature	Direct temperature measurement (termometry)	ŠPP INO.M.170 (STN 75 7375)	Testing on site at a customer
9	The workplace atmosphere and indoor atmosphere	Relative humidity of the air rh	Measurement of Relative humidity of the air	IP-3 (STN EN ISO 7726)	

notice:
1 - AHEM - Acta hygienist, epidemiologist and microbiology
2 - N/I - expression of opinions and interpretations
3 - AAS-ETA - atomic absorption spectrometry with electrothermic atomization
4 - IP - internal regulation
5 - SOP Standard Workflow

A2-4 Specification of the activities in which the laboratory with fixed scope carries out sampling

Item	Object			Method		Other specifications
	Subject	Property	Place of sampling	Type / principle	label	
1	Working air	stiff aerosol	Working environment	Subscription to membrane filters	EPA 235/01 (IP 123/5)	

Item	Object			Method		Other specifications
	Subject	Property	Place of sampling	Type / principle	label	
2	Sludges	Characteristics listed in the scope of accreditation of the testing laboratory under No. x – z and procurements performed for the customer, subcontractor and	ČOV[1], sewerage, storage and sewerage structures	spot sample, mixed sample (manual sampling)	IP No 13[2] (STN EN ISO 566-1 STN EN ISO 5667-13 STN EN ISO 5667-15 STN EN ISO 5667-16)	

notice
1 - wastewater treatment plant
2 - IP No.13 - internal regulation marking ...

Examples of filling tables

A2-1 Specification of the operation of the test laboratory with flexible scope

Item	Test object		Established method		Other specifications (scope, uncertainty, purpose, modification/validation, opinions/interpretations, etc.)
	Subject /Matrix /Environment	Property /Parameter / Indicator/Analyte	Principle /Type	Label	
1	Water: - drinking water - waste water	count faecal streptococcals	Iconically (quantitative)	STN ISO 12345 STN EN ISO 65789 STN EN 12786	N/I [1]
2	foodstuff: -meat and meat products	Metals [(2)]	AAS-ETA	IP 65/2 (STN EN ISO 76986)	

Flexibility does not apply to changing the principle of the methods used in a given flexible scope.

☒ The laboratory maintains an up-to-date list of all test methods with a flexible scope of accreditation at www.cab.sk/flexible-accreditation/

The principle of flexibility can be used by the laboratory within the framework of:

☒ objects/matrices/environments

☒ properties/parameters/indicators/analytes
☐ measuring ranges and measurement uncertainties
☒ modifications to the methods and procedures used for testing
☒ identification of the methods and procedures used for testing

notice:
1 - N/I - expression of opinions and interpretations
Metals (2) – Pb, Cd, Hg, Fe, Zn

A2-4 Specification of activities where a flexible-scope laboratory carries out sampling

Item	Object			Method		Other specifications
	Subject	Property	Place of sampling	Type / Principle	Label	
1	Water and associated matrices - groundwater - drinking water	Characteristics listed in the scope of accreditation of the testing laboratory under No. x – z and procurements performed for the customer, subcontractor and	Wells, springs, boreholes, tap, distribution network	Point, integrated sample	NRL/ALL-SOP/1[1] (STN EN ISO 5667-1 STN EN ISO 5667-3 STN EN ISO 19 458 STN ISO 5667-11 STN ISO 5667-18) (STN EN ISO 5667-1 STN EN ISO 5667-3 STN ISO 5667-5 STN ISO 5667-11 STN EN ISO 19 458)	

The laboratory may modify and validate those test methods in the accreditation field, while maintaining the sampling principle.
Flexibility does not apply to changing the principle of the methods used in a given flexible scope.
☒ The laboratory maintains an up-to-date list of all test methods with a flexible scope of accreditation at www.cab.sk/flexible-accreditation/

The principle of flexibility can be used by the laboratory within the framework of:
☒ objects/matrices/environments
☒ properties/parameters/indicators/analytes
☒ modifications to the methods and procedures used for sampling
☒ identification to the methods and procedures used for sampling

notice:
1- NRL/HES-SOP - internal regulation marking ...

9.3 ANNEX A3 – GUIDELINE FOR MEDICAL LABORATORIES

In general

Form of activities specification for medical laboratories applying for accreditation is given in the following tables. By filling relevant Tables the applicant specifies activities which applies accreditation for and which will be after the completing of accreditation process, 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 to 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.. 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 Table A3-2 for activities covered under flexible scope. Table A3-2 for laboratory with flexible scope will be the basis for the List managed only by the laboratory.

Laboratory completes Table A3-3 in the case when it also applies for the flexible scope of accreditation.

In cases where the medical laboratory carries out sampling, it fills in the Table of activity specification A3-4.

Laboratories do not fill in those tables that are irrelevant for their activities for accreditation.

Table templates for activities specification/accreditation fixed scope of a medical laboratory:

The tables as specified by the laboratory are completed: A3-1, A3-4

Table A3-1

Laboratory:	**with fixed scope** ☒

Specification of activities for fixed scope of a medical laboratory

Item	**Object of examination**		**Established method**		**Other specification (range, uncertainty, purpose, equipment, etc.)**
	Biological sample/ Matrix	**Analyte/ Parameter**	**Principle**	**Identification**	
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/Parameter“.

The vertical field „Object of test“ is divided into two fields:
- „ Biological sample/Matrix“
- „Analyte/Parameter“.

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

Column 3:
“Analyte/Parameter“ is specified in this column. Basically, it can be a determination of several properties of the same matrix by using respective method or a certain property of different matrices. In the second case in column 3 it is possible to merge more analytes/parameters into one field of the table.

The vertical field „Applied method“ is divided into two fields:
- „Principle“
- „Identification“

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

Column 5:
This column gives the designations of the methods used, identifying whether it is a standard method, a modified standard method or a method of its own, as follows:

- as regards the standard method and the entity does not have an internal operating procedure in place to perform the test because it operates exactly according to the recommended document, an indication of the recommended document (RD) or other official regulation shall be provided, e.g.:

RD xxxx

- in the case of an unmodified standard method rewritten in an internal laboratory regulation, the indication of the recommended document shall be indicated below and below it in brackets an indication of the internal regulation, e.g.:

  RD xxxx
  (IP yyy)

- in the case of a modified standard method or a downloaded method documented in an internal laboratory regulation, the designation of the internal regulation and below it in brackets shall indicate the recommended document (s) on which the procedure is based, e.g.:

  IP yyy
  (RD xxxx; citing literature)

  Note: the location of the "quoted literature" may be the reference where the citation is located.

- in the case of a laboratory-developed method, only its internal marking shall be provided, e.g.:

  IP yyy

Where a laboratory uses several recommended documents/regulations/procedures to determine the relevant characteristics, only the basic regulation/basic rules shall be indicated in column 5 and the other related rules/standards shall be entered, where appropriate, in column 6 'Other specifications'.

Where a laboratory uses several methods to determine the relevant characteristics, only the basic regulation(s) shall be indicated in column 5 and the others shall be entered, if necessary, in column 6 'Other specifications'.

Column 6:
In this column important specifications are mentioned which with their character do not belong to previous columns. E.g. when using qualitative methods, under the principle of the method, it shall be given in brackets "(qualitative method / examination)" or a similar designation. In the case of medical laboratories, the table does not require the expression of opinions and interpretations to be indicated separately.

Table A3-4

Sampling:

Laboratory:	**with fixed scope** ☒

Specification of the activities in which sampling is carried out by the laboratory

Item	Object			Established method		Other specifications
	Biological sample/Matrix	Analyte/ Parameter	Place of sampling	Principle	Identification	
1	2	3	4	5	6	7

The specification in this field of activity of the medical laboratory is completed by a laboratory, which, in addition to examinations, also carries out sampling.

Instructions for filling in the Table:

Column 1:
As with the fixed scope of accreditation A3-1.

The vertical field "Object" is divided into three fields, namely:
- " Biological sample/Matrix ",
- " Analyte/Parameter" and
- ' Place of sampling '.

Column 2:
As with the fixed scope of accreditation A3-1.

Column 3:
This column shows the analyzed parameters of the biological materials taken listed in column 2. If the specification refers to the examinations already listed in Table A3-1, it is sufficient to indicate the item number of this table under which the parameters for which sampling is performed are located.

Column 4:
The sampling points are specified, such as 'sampling room', 'medical specialist office', etc.

The vertical field "Method" is divided into two fields, namely:
- " Principle" and
- " Identification ".

Column 5:
This column indicates the principle of the sampling method used. The specification of the principle of method should be sufficient to distinguish it from other methods used for the purpose (eg "capillary finger sampling, venous sampling", etc.). The specification of this part of the table should be identical to the information given in the standard or other sampling method used.

Column 6:
Fill in according column 5 for the fixed scope of accreditation A3-1.

Column 7:

This column sets out important specifications which, by their nature, do not fall within the previous columns, in particular:

a. Information on subcontractors conducting testing of samples taken

Note: Subcontractors must meet the requirements of the current ISO 15189 standard.

b. Sphere for which sampling is carried out.

c. Specific conditions under which sampling may be carried out

d. Other regulations relating to sampling carried out not specified in the previous columns.

e. Further relevant information to complement the complexity of the data in the relevant horizontal field.

Note: If it is necessary to give explanatory notes or notes to certain items in the table, they shall be marked in the appropriate field with a serial number and shall be listed below the table. The table should contain only specifications.

Table templates for activity specification/scope of accreditation of a medical laboratory with a flexible scope:

The tables as specified by the laboratory are completed: A3-2, A3-3, A3-5

Table A3-2

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

Laboratory:	**with a flexible scope** ☒

Item	**Object of examination**		**Established method**		**Application field**	**Other specifications (scope, uncertainty, purpose, equipment, etc.)**
	Biological sample/Matrix	**Analyte/Parameter**	**Principle**	**Identification**		
1	**2**	**3**	**4**	**5**	**6**	**7**

Below the table, flexibility is clearly defined by selecting from the options:
Flexibility does not apply to changing the principle of the methods used in a given flexible scope.
☐ The Laboratory maintains an up-to-date list of all examined methods with a flexible scope of accreditation on the www.cab.sk/flexibile-acreditation/

The principle of flexibility can be used by laboratories within the
- ☐ biological samples/matrices,
- ☐ analytes/parameters,
- ☐ devices (other specification)
- ☐ methods (other specification)
- ☐ identifications of the method used for examination.

Instructions for filling in the table:

Column 1:
As with the fixed scope of accreditation A3-1.

Column 2
As with the fixed scope of accreditation A3-1.
The specification may be given more generally.

Column 3:
As with the fixed scope of accreditation A3-1.
The specification may be given more generally.

Column 4:
The column "Principle" of the developed methods indicates the framework identification of the principle of the method, sufficient to distinguish from other principles of methods, e.g. photometry, spectral analysis, electrochemistry, etc.

Column 5:
As with the fixed scope of accreditation A3-1.

Column 6:
The specification of the spheres where the use of the method under development is envisaged or determined, such as "biochemistry", "hematology", "genetics" etc. (see Chapter 9.4, Annex B, section 3.1 Areas of activities of medical laboratories)

Column 7:
This column provides, where appropriate, further up-to-date specifications concerning e.g. validation of developed methods, envisaged standardization, etc.

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

Personnel competent to modify and validate methods/develop new methods during the validity of accreditation

First and last name, titles	Ability to modify and validate methods/develop new methods - - Item in activity specification No
1	2

Instructions for filling the table:

Column 1:
The names of persons competent to modify and validate testing methods/develop new methods during the validity of the accreditation certificate shall be given.

Column 2:
Items from Tables A3-1 or A3-2 for which the persons concerned are competent to modify and validate test methods during the validity of the accreditation certificate shall be provided.

Examples of completed tables

A3-1 Specification of activities of a medical laboratory with a fixed scope of accreditation:

Item	Object of testing		Established method		Other specification (range, uncertainty, purpose, equipment, etc.)
	Biological sample/Matrix	Analyte/ Parameter	Principle	Identification	
An example from the field of biochemistry:					
1	Serum	Albumin	Photometry	PL-albumin Biovendor (ŠOP No.40) [1]	Equipment XX-
2		Alkaline phosphatase			-
3		Amylase			-
4	Serum	IgM antibodies of toxoplasm	ECLIA		
5		IgG antibodies of toxoplasm			
6	Cord blood	antibodies of toxoplasm	ELIFA		

Notice:
ECLIA: Electrochemical immunoassay
ELIFA: Enzyme immunofiltration test
ELISA: Enzyme immunoassay analysis
ŠOP/ŠPP: Standard operating procedure/Standard working procedure˘

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

item	Object of examination		Established method		Application field	Other specifications (equipment, etc.)
	Biological sample/Matrix	**Analyte/ Parameter**	**Principle**	Identification		
Example of the flexible scope of accreditation of the biochemical laboratory:						
1	Serum, blood	antibodies of Streptococcus pneumoniae	Immunochromatography	ŠOP X/Z	Clinical biochemistry	IVD-MD instructions (Ref. ZZ including version code)
Example of the flexible scope of accreditation of a genetic laboratory using NGS technology:						
1	Peripheral blood	Nucleic acid (DNA)	extraction of NA	ŠPP X/Z	Laboratory diagnostic in medical genetics	Qualitative method
2	Amniotic fluid (native) nucleic acids	Prenatal test / DNA / chromosomal aberrations	PCR / fluorescent PCR	Code of ŠOP version Ref. OO	Laboratory diagnostic in medical genetics	Name od device/ Analytical platform (quantitative fluorescent PCR

notice:
ŠOP/ŠPP: Standard operating procedure/Standard working procedure
Flexibility does not apply to changing the principle of the methods used in a given flexible scope.
☐ The Laboratory maintains an up-to-date list of all examined methods with a flexible scope of accreditation on the www.cab.sk/flexibile-acreditation/

The principle of flexibility can be used by laboratories within the
☐ biological samples/matrices,
☐ analytes/parameters,
☐ devices (other specification)
☐ methods (other specification)
☐ identifications of the method used for examination.

A3-3 Specification of activities for which laboratory performs sampling

Laboratory	with fixed scope	with a flexible scope
	☒	☐

Item	Object			Method		Other specifications
	Biological sample/Matrix	**Analyte/ Parameter**	**Place of sampling**	**Principle**	**Identification**	
Example 1:						
1	Capillary blood	Glucose	Income room - sampling part	Taking blood from finger capillary	Operating manual Super GL (SOP No. 21)	

Item	Object			Method		Other specifications
	Biological sample/Matrix	Analyte/ Parameter	Place of sampling	Principle	Identification	
2		Erythrocytes			Operators manual Sysmex K1000 (SOP No.35)	
Example 2:						
1	Blood	1-41 of scope	Sampling room	Collection of venous blood	(SOP 42, Blood collection)	

a.

notice:
1 - SOP – standard operation procedure

9.4 ANNEX A4 – GUIDELINE FOR PROFICIENCY TESTING PROVIDERS

In general

Specification of the PT provider activities are specific. Specification of activity, where the „Field“ and „Subject of proficiency testing” represent the scope of accreditation. The information of compared properties, parameters and indication of the PT program, etc. for given item of test are 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.

Table templates for activity specification /scope of accreditation of the proficiency testing provider

Table A4-1

Proficiency testing Provider:	has a laboratory ☐	provides laboratory services by subcontracting ☐

Item	Field	Subject of proficiency testing	Compared properties (parameters, indicators, analytes), Range of compared values (informative)	Indication of the proficiency testing program	Other specification
1	2	3	4	5	6

Instructions for filling the table:

Column 1:
Serial number of the field mentioned in column 2

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 ...", types of ionizing radiation meters", "sampling 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 the PT provider is responsible and it depends for example on his relevant subcontractor.

Column 5:
This column "Proficiency test program designation" indicates the general proficiency test program code (s) under which the program is implemented.

Column 6
In this column „Other specification" only informative piece of information are listed 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)	Indication of the proficiency testing program	Other specifi cation
		Example 1			
1	Beverages	Alcoholic Soft and energy drinks, b.	Alcohol content, Total dry extract, Sugar Acetaldehydes,	IP No./year	Once a year
2	Water	c. Waste water	Taking samples for determination of heavy metals and polycyclic aromatic carbohydrates in full range of concentration in WW[1]	MPS-OOV-mm/year	Twice a year
		Example 2			
1	Lenght	end scales angle gauge dashes	- End gauges until 1000 mm - linear measure until 2000 mm	MLPM/SLM/x/year	once a two years
2	Temperature and heat	Calibration of of thermometers: - electronical thermometers, - temperature transducers	until 500 °C until 660 °C	MLPM/K/x/year	
	Example 3				
1	Road and construction materials	Asphalt	Softening point penetration	VUCES-PTA/AZ/year/x	once a two years
2		Aggreggates	Particle size distribution Shape index	MC/mm/year	once a five years

Notice:
[1] – WW – waste water

9.5 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.

Note:
When the laboratory is accredited for 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:
If the laboratory is accredited for a fixed and flexible scope, the scope of accreditation must be defined separately for each type.

3. Medical laboratories

3.1 Field of activities of medical laboratories

- clinical biochemistry
- clinical microbiology (bacteriology, parasitology, mycology, virology)
- clinical hematology and transfusiology
- clinical immunology and allergology
- medical genetics
- clinical pathology

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.

… laboratory is competent to perform laboratory examination and testing of biological samples of human origin using virological, serological, molecular biological, biochemical and histological methods for diagnosis of enterovirus infections and detection of antibodies against them; infectious agents causing viral hepatitis and antibodies against them; human immunodeficiency viruses (HIV) and antibodies against them and detection of prion disease pathogenic agent including CJD specific mutation within the accreditation scope.

Note:
If the laboratory is accredited for a fixed and flexible scope, the scope of accreditation must 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 programs 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.

***