



SNAS

SLOVENSKÁ NÁRODNÁ AKREDITAČNÁ SLUŽBA

METHODICAL GUIDELINE FOR ACCREDITATION

**INTERLABORATORY COMPARISON IN
CALIBRATION LABORATORIES**

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1 INTRODUCTION

This methodical guideline of accreditation determines requirements for inter-laboratory comparison measurements in calibration, responsibility for their organization and provides instruction related to planning, preparation and accomplishment of measurement as well as elaboration of a report.

The guideline consists of procedures for organization of inter-laboratory comparison measurements of accredited laboratories, testing laboratories providing their own calibration and inspecting bodies performing calibration as a part of the inspection.

2 ABBREVIATION USED

PTP - Provider of inter-laboratory comparison - subject which is able to prove the fulfilment of requirements for providers of proficiency testing schemes according to the document ISO/IEC 17043e. g. by accreditation.

PT - Proficiency Test – determining the calibration or testing proficiency of a laboratory by suitable method – comparison measurement.

ILC - Inter-laboratory comparison – organizing, performing and evaluation of calibration or test of the same or similar measuring device by two or more laboratories under defined conditions.

Proficiency of a laboratory - demonstration of proficiency of a laboratory to perform its activity within the declared scope.

Reference laboratory – laboratory determining reference values for the purposes of the comparison measurements provided that the SNAS policy related to measurement sequence shall be followed.

3 RELATED DOCUMENTS

- ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17043 - Conformity assessment -- General requirements for proficiency testing
- ISO 13528 - Statistical methods for use in proficiency testing by interlaboratory comparison

4 SNAS POLICY ON PROFICIENCY TESTING AND COMPARISON MEASUREMENTS

The ISO/IEC standard 17025 „General Requirements ...“ requires that the laboratories shall have controlled procedures for monitoring of test and calibration validity. One of very important instruments to prove the technical proficiency of a laboratory is its participation in inter-laboratory comparison tests. The proficiency tests as well as inter-laboratory comparison measurements in calibration are the basic component of assessment procedure.

The SNAS policy is based on the above mentioned facts. Demonstration of the proficiency based on results of inter-laboratory comparisons is a basic criterion during assessment of the fulfilment of accreditation requirements. So it is necessary to participate in the inter-laboratory comparisons and proficiency tests in their own interest.

5 PURPOSES AND BASIC TYPES OF COMPARISON MEASUREMENTS

Inter-laboratory comparison measurements are aimed to verify the proficiency of the laboratory activity performances inclusive of measurement uncertainties mentioned. They may be organized on national or international level and they are a very important SNAS instrument for granting or maintaining the accreditation.

Activities within national ILCs are compliant with this MSA.

The following types are used:

- a) Circular comparison – it is the circulation of item under calibration successively among the participants of the inter-laboratory comparison beginning and ending in a reference laboratory;
- b) Star-shaped comparison – the item under calibration is returned into reference laboratory for any termination of measurement by each participant or each participant gets the item under calibration which was previously measured by the reference laboratory;
- c) Mixed comparison – the item under calibration is sent to two or three participants gradually and is returned back to the reference laboratory and after measurement in the reference laboratory the calibrated item is sent to other group of participants, etc. And the overall measurement ends in the reference laboratory;
- d) Bilateral comparison - it is the comparison to be used in accreditation process between the laboratory under assessment and a laboratory to be determined by the assessor as reference one.

Selection of comparison measurements shall be coordinated in accordance with accreditation requirements.

6 ACCEPTANCE OF COMPARISON MEASUREMENTS

The comparison measurements is accepted, if the provider of a comparison measurement is an accredited PT body or any other suitable provider fulfilling the requirements of ISO/IEC 17043.

The SNAS accepts proficiency test and comparison measurement results even for laboratories participating in comparison measurements organized by other providers fulfilling the ISO/IEC 17043 requirements for providers and supports active participation of laboratories in even on regional ILCs organized by EA, BIPM, ILAC, APLAC, or by accreditation bodies of other countries in accordance with the EA regulations.

The SNAS may, but need not have a respect to programs and their results, if the relevant program was not registered in SNAS previously and if regularity according to guidelines of ISO/IEC 17043 was not assured.

Results of comparison measurements is to be submitted by the laboratory within the accreditation process. Unsuitable results shall not be accepted.

In the case of unsuitable results, it is necessary to submit corrective measures and their solutions.

Results of comparison measurements for review of proficiency of a laboratory are accepted within one accreditation cycle.

7 PARTICIPATING LABORATORIES

The comparison measurement is preferably determined for laboratories which are already accredited by SNAS for relevant measurements, are in the reviewing process for the purposes of accreditation or they are prepared for accreditation. In the case that any non-accredited laboratory takes part in comparison measurement, the provider shall ascertain if such laboratory has sufficient experience and suitable measurement conditions to avoid damages of measurement devices which are subject matter of the proficiency tests. For laboratories accredited by SNAS is the participation in the program obligatory, if the laboratory does not submit results of any other suitable program in the given year and does not prove that further participation will be extreme financial burden of the laboratory.

Foreign laboratories may participate in the comparison measurement, if this program was offered by any foreign partner

The program provider, reference laboratory do not take part in the comparison measurements.

A laboratory which is associated with the program provider may participate in the comparison measurement program, if the measurements results are sent to the SNAS for coding and sending them back to the provider for review.

Participating laboratories shall have mutually comparable level of measurements in question. Including laboratories with very high or very low value uncertainty of measurements in question shall be considered separately.

8 PRINCIPLES OF FINANCING OF COMPARISON MEASUREMENTS

Each participating laboratory meets its own costs connected with the comparison measurements, if nothing else was agreed for the relevant comparison measurement.

Participating laboratories meets other unavoidable costs connected with comparison measurements such as hire for device lease, measuring device transport, travel costs of accompanying courier, insurance, independent review by third party, etc. (for instances see the Annex F) in the form of participating fee. The provider of the relevant comparison measurement program shall prepare the comparison measurement budget and the Program Consultative Group discuss it. If necessary, the budget shall consider even the solution of situation when a measuring device being a subject matter of the comparison measurement will be damaged or destroyed.

9 SELECTION OF EQUIPMENT AND INSTRUCTION FOR MEASUREMENT

The measuring device to be used for comparison measurements shall be sufficiently robust and resistant with stable metrological properties preferably so that its calibration will be adequately valid during the overall comparison measurement. If it is not the case, it is

necessary to perform measuring device re-calibration during the comparison measurements even several times (star-shaped or combined comparison program). Before start of the program the provider shall state the stability of used measuring device by measurement and use of relevant statistical design. The variation of measured values shall be inside stated value by provider during the design of the program. It have to be taken in account the the value of reachable uncertainty of results of participants of the program.

It is necessary to select such measuring device and such procedures, that the overall measures shall preferably not take more than 8 work hours in each laboratory. To this time, it is necessary to add the time required for update and preparation with the type of comparison measuring device, calibration method and measuring device stability shall be considered.

10 PROVIDER'S ROLE

The provider of the national program of the comparison measurement has the following tasks:

- a) Propose preliminary instructions and produce financial calculation of costs;
- b) Issue final instruction for the participants;
- c) Determined laboratory sequence and the method of measuring device transport;
- d) Have available the item under calibration(own, leased or hired measuring instrument);
- e) Assure the calibration of measuring device in suitable laboratory so that the SNAS policy in the area of measurement sequence shall be followed;
- f) Have overview on comparison measurement progress;
- g) Collect from the participants the measurement results and assure their independent review;
- h) Prepare the report draft and let it approve by the participants of the comparison measurement;
- i) Prepare final report;
- j) Inform the SNAS about delayed or any other non-expectable events and, in cooperation with the SNAS, take adequate measures;
- k) Cooperate with reference laboratory in solving of special tasks of comparison measurements very closely, if required.

The provider shall keep secrecy about all information related to individual laboratories durably.

The provider is responsible for selection of suitable reference laboratory respecting the aspect that eventual insufficient ability of the reference laboratory to determine the reference value shall not damage the evaluation of proficiency of participating laboratories.

The provider of the national ILCs shall prepare the program proposal which shall consist of data mentioned in the Annex B as the minimum.

It is important to follow the time schedule of the comparison measurement. The provider of the relevant comparison measurement is responsible for time schedule observance.

11 THE ROLE OF THE REFERENCE LABORATORY

A reference laboratory determined reference values in agreed measurement points according to approved program of comparison measurement.

Reference laboratory may perform, based on a contract, independent evaluation of comparison measurement results for the Provider of the comparison measurement as third party, if it is not the provided of the comparison measurement directly.

If the provider of the comparison measurement is the reference laboratory simultaneously, a special sponsor of ILCs shall review the comparison measurement results.

12 PREPARATION OF THE SNAS COMPARISON MEASUREMENTS

The provider itself, or if required, in cooperation with reference laboratory (special sponsor) assures the elaboration of preliminary instructions for laboratories.

The above mentioned instructions shall consist of the following information as a minimum:

- a) Name and address of responsible employee of the provider;
- b) Name of reference laboratory;
- c) Description of measuring device (s) – fabrication, type, series No., dimension, weight, packing, etc. of all measuring device components as well as dimension of the overall packing.);
- d) Complete list of packing content, packing dimension and weight (inclusive of manuals etc.), Annex D);
- e) The instruction shall consist of information about prescribed method, if it is possible to use method normally used in the laboratory or, if required, calibration procedure;
- f) Measurement points;
- g) All special transport recommendations;
- h) All special recommendations related to handling the device;
- i) Technical manual consisting of all necessary device data (e. g. its thermal index, etc.)
- j) If required, all special instructions for recording of results (preparation of forms for result summary is required, e. g. see Annex C).

After considering all eventual comments, the provider shall prepare the time schedule with the maximum circulation time being not exceeded as follows:

- 9 months when organizing the national ILCs;
- 12 months when organizing the regional ILCs

The time to be allowed to spend by individual laboratories depends of the magnitude to be measured. One, maximum two months (inclusive of transport) are recommended.

Definitive instruction shall be sent by the provider to the program participants before starting the comparison measurement.

If suitable, the comparison measurement shall be performed so that the measuring device and the relevant instructions are transported among laboratories by an appointed expert working as a carrier simultaneously.

13 INSURANCE

An agreement shall be concluded between the measuring device owner and the provider for the case of damage or loss of it.

If nothing else is agreed, the risk of damage or loss of the device shall be born by the provider. This risk may be covered by suitable insurance.

14 CARRYING OUT OF SNAS COMPARISOM MEASUREMENTS

The comparison measurements are organized and evaluated anonymously. The identification of participating laboratories during its duration is known only to appointed person of the provider being responsible for the comparison measurement or coordinating person of SNAS prospectively.

Participating laboratories are responsible for transport of measuring device. The transport method shall be selected by the provider according to the packing content. The packing may be transported by normal transportation method, special transportation method (by courier mail) or by a representative of the accreditation body.

Each participant of the comparison measurement shall inform the provided in writing (or by facsimile) about acceptance and inspection of the measuring device packing. If nothing else is determined (e. g. delivery by a currier), the laboratory shall send, after accomplishing the measurements, the measuring device to next measurement participant to be determined by the provider and, simultaneously, the sending laboratory shall inform the provider about it.

Each participant of the comparison measurement shall calibrate the measuring device by usual method or if required, determined the calibration method or procedure shall be prescribed by provider. The existence of reference values with relevant uncertainties is required to have the possibility to compare measurement results of laboratories.

Preliminary reference values determined in the reference laboratory by the calibration of the measuring device shall be delivered to participants of the program within three weeks after acceptance of results and certificates from all participants provided that the measuring device stability is proved as adequate and the above mentioned reference values may be used for comparison purposes.

If required, the measuring device shall be measured in the reference laboratory after finishing of each measurement round so that the stability of the measuring device might be monitored and that it could be confirmed that the measuring device is not damaged.

In the case of any deviation to be caused by e. g. insufficient stability of measuring device, the reference laboratory shall specify definitive reference values. If required, it is possible to determine various reference values for various laboratories considering the heterochronism of values.

15 RESULTS AND RELEVANT UNCERTAINTIES

Participating laboratories shall send the measurement results within two weeks after finishing the measurements to the person mentioned in the instruction of the provider sent to the participants.

If nothing else is stated in the measurement instruction, each participating laboratory shall elaborate a calibrate certificate meeting the requirements of ISO/IEC 17025. The measurement results shall be entered into the prescribed form – tables (e. g. Annex C) and

together with the certificate, they shall be sent to a prescribed address. Measurement uncertainties shall be determined according to the procedure mentioned in the EA-4/02 (for translation see the MSA L/12). Further information may be requested, if necessary for interpretation of measurement results and if the provided come to a conclusion that such information may be useful. Additional information shall be stated in standard forms which are sent together with the measurement information.

If the measurement uncertainty will significantly differ from the measurement uncertainty stated in the accreditation scope of a laboratory (CMC), the relevant laboratory shall explain this fact.

The measurement results of laboratories are compared with reference values determined in the reference laboratory.

Comparison measurement results are of confidential character and so they are available in an encoded form. Each laboratory participating in comparison measurements will be informed about its own individual code only. The accreditation body eventually authorization body are entitled to know the above mentioned codes, if it is the question of comparison measurements in controlled area. Comparison measurement results may be published with the prior written approval of all of participating laboratories only.

16 RESULTS EVALUATION

Encoded results are evaluated either by the provider itself or in cooperation according to the procedure mentioned in the Annex E.

Estimated time, which the provider needs to take for elaboration of the comparison measurement results shall not exceed the period of approximately one week.

17 DRAFT REPORT

The report to be elaborated by the provider, at need in cooperation with the reference laboratory, shall include as follows:

- a) Identification of the comparison measurement, name and number;
- b) Reference values in approved measuring points;
- c) Evaluation of stability measurement of measuring device used;
- d) Identification Code of a participating laboratory and participating laboratory comparison measurement results together with uncertainties;
- e) One copy of comparison measurement instruction;
- f) All comparison measurement results, which seem to be unacceptable (for evaluation method see the Annex E);
- g) All eventual deviations from originally approves time schedule and deviation reasons.

The above mentioned information are to be added by diagrams for each measured parameter.

To keep confidentiality, no list of participants is stated in the report.

In the report draft, all problems are evaluated, which occurred in connection with the measuring device and measuring device transport, stability or suitability for given measurements. Measurements methods and laboratory equipment used shall be evaluated too.

Results with the values of associated uncertainties shall be elaborated in the form of tables. If required, a comment shall be added to the uncertainty values. Finally, conclusions such as how the overall state of the magnitude measurement is in the laboratory as a whole together with recommendations for further inter-laboratory comparison measurement shall be mentioned.

Within two months after measurement finish, the provider shall send the draft report to the comparison measurement participants for commenting.

If appropriate written comments to the draft report shall be submitted by participants within one month to the provider. It is not possible to request additional change of comparison measurement result evaluation, if errors were not provably caused by the provided during transcribing of the comparison measurement results only. As a base, the comparison measurement results sent, even if the error was made by the participant during transcribing.

The provider shall discuss received comments within 2 months from dispatching of the draft proposal at the very last.

18 CORRECTIVE ACTIONS

The provider is obliged to make the SNAS familiar with the comparison measurement results.

A laboratory with unacceptable comparison measurement results shall take corrective actions.

Results mentioned in the reports serve for control of the relevant accredited laboratory during the surveillance. During the surveillance, actual results reached by the laboratory under surveillance visit are examined and in the case of insufficient results, corrective actions taken are assessed.

In the case that a laboratory is not successful in two inter-laboratory comparison measurements or proficiency tests repeatedly, the SNAS shall consider further validity of the accreditation certificate and consider the suspension of accreditation in the given calibration field.

In the case of unsatisfactory comparison measurement results of several laboratories, the SNAS shall take measures in the form of proficiency test or comparison measurement repetition, organizing of training in the given field, validation of the calibration methods, etc. Restrictive measures will be used in repeated cases of insufficient results of the relevant laboratory.

In the case of laboratories applying for accreditation, the above mentioned results shall be considered for the purposes of decision-making related to accreditation. Corrective actions are in competence of the SNAS and are not included in the report.

19 FINAL REPORT

If no comments are submitted to the draft report, then the draft report is considered as a final report.

If submitted comments to the draft report, the final report shall be prepared considering all comments within two months after discussing them with the provider. The report shall include the same articles as the draft one but it shall be supplemented by accepted comments and, if required, information related to corrective actions.

If the program results require, the SNAS shall be responsible for consequence implication against accredited laboratories based on final report results or any further measures to be taken.

The provider is responsible for preparation of sufficient report copies so that each participating laboratory shall receive one report copy.

20 COMPARISON MEASUREMENTS CARRIED OUT DURING ASSESSMENT FOR THE PURPOSES OF ACCREDITATION

Comparison measurements are made as a part of assessment if the laboratory did not prove its performance by its participation in officially acknowledged inter-laboratory comparison measurements. This comparison differs from the above mentioned inter-laboratory comparison measurements so that it is bilateral (assessed laboratory and the reference one) only.

The bilateral comparison measurement is performed as a part of assessment. The comparison measurement provider is usually the technical assessor directly together with the lead assessor. The technical assessor organizes the overall measurement. He/she determines the measuring device, the reference laboratory, time schedule of measurement and all of the data are to be submitted by him/her to the assessed and reference laboratories in writing.

As a reference laboratory, a laboratory accredited in relevant range of accreditation or relevant laboratory of suitable national metrological institute of the recognition agreement signatory may be selected.

The measuring device calibration in the reference laboratory is performed in the range to be determined by the assessor as any other calibration requirement in the laboratory. Costs connected with the measuring device laboratory bears the assessed one.

After measuring device calibration in the reference laboratory, the measuring device shall be delivered to the assessed laboratory on its own costs and then the measuring device calibration shall be performed. The transport method shall be agreed with assessed laboratory.

In some cases, if it is practical, the assessor may ask to perform the calibration under his/her presence on the assessed laboratory directly. In such case, the assessor may bring the measuring device individually.

Calibration results from the reference and assessed laboratories shall be evaluated by the assessor using the method mentioned in the Annex E. Evaluated results shall be discussed by the lead assessor and the technical assessor during the final evaluation with the assessed laboratory and they shall propose eventual comparison measurement repetition, if required. About such discussion, written minutes shall be produced.

Based on the comparison measurement results, the performance of the assessed laboratory in the required activity scope either will be or will be not confirmed or eventual reduction of the required activity scope will be decided. If occurring repeated negative results of comparison measurement, the assessment finish with negative recommendation to disapprove the accreditation in the relevant calibration field shall be proposed. The assessed laboratory shall be informed about all of results immediately.

Obtained results shall be elaborated in the graphical or tabular form together with associated uncertainties and verbal comment in the partial report stating the performance of the assessed laboratory to perform the assessed activity.

21 ANNEXES
ANNEX A

Recommended terms for implementation of the individual steps of the inter-laboratory comparison measurement.

Activity	Time/ term
1 Planning and preparing *	
1.1 Measurements in each laboratory	8 hours
1.2 Result evaluation by the provider	1 week
1.3 Measuring device circulation period belonging to one laboratory inclusive of transport	1 to 2 work weeks
1.4 Packing dwell in each laboratory	maximum 2 weeks
1.5 Total circulation period	maximum 9 weeks
2 Implementation	
2.1 Sending the calibration certificates to the provider	Within 2 weeks after measurement finish
2.3 Draft report related to results of participating laboratories	1 month
2.4 Preliminary reference values sent to participating laboratories	Within 3 weeks after receiving the calibration results
3 Reports	
3.1 Sending the draft report to the measurement participants	2 month
3.2 Submitting written comments to the provider	within 1 month
3.3 Commenting the draft report at the provider P	within 2 months after sending the draft report
3.4 Preparing the final report	within 2 months after discussion at the provider

*Note: Preparation of the inter-laboratory comparison measurement shall be assured so that the overall period of it does not exceed 9 months.

ANNEX B
Proposal for new comparison measurement

1. Proposed by:
2. Provider:
3. Quantity to be measured:
4. Item (measuring instrument) selected for comparison measurement, item owner:
5. Prescribed measurement points and ranges:
6. Reference laboratory:
7. Stability and resolution of the selected measuring instrument (if required):
8. Laboratory own measurement methods or prescribed procedures:
9. If prescribed, list the reasons to do it:
10. Transport method:
11. Proposed date of start and finish of the comparison measurements:
12. Expected date if final report distribution:
13. Additional notes:

ANNEX C
Instance of result presentation

RESULT OVERVIEW		
Measured values	Expanded measurement uncertainty	The best measurement capability

Short description of the expanded uncertainty calculation (uncertainty budget):

Notes to the deviation of determined expanded uncertainty from the BMC, if appropriate:

ANNEX D

List of things included in the packing

- Measuring instrument(s) to be calibrated;
- Auxiliary equipment necessary for correct calibration accomplishment;
- Eventually necessary manuals to the apparatus;
- Sufficiency of forms for confirmation of packing receipt;
- Measurement instruction;
- List of things included in the packing, identification number of the apparatus(es) and list of auxiliary equipment and other things mentioned in the Annex.

ANNEX E

Examples of result evaluation

Examples of some statistical method of comparison measurements result evaluation are mentioned in the ISO 13528.

- Suitable method for quality evaluation of measurement results based on ISO 13528 is the E_n error calculation normalized to given uncertainty, i. e.:

$$E_n = \frac{x_{lab} - x_{ref}}{\sqrt{U_{lab}^2 + U_{ref}^2}}$$

Where x_{lab} is the measurement result of the participated laboratory, how it was stated in the calibration certificate, x_{ref} is the reference value of the measuring device data in the time where the x_{lab} value was measured, U_{lab} is expanded uncertainty x_{lab} so, who it is stated in the calibration certificate. U_{ref} is expanded uncertainty x_{ref} , which shall include the tolerance of the relevant metrological characteristics of the measuring device during the comparison. .

E_n absolute values shall be lower than one, so that the measurement shall be acceptable.

- Beside tabular representation of results, the results may be processed in graphical form marking the measured values and expanded uncertainty around the measured valued by abscissa form.
- In some cases, a suitable method of result assessment is the combination of E_n normalized error calculation based on ISO 13528 and Z-score according to ISO 13528.

ANNEX F
Examples of items included in calculation of price for comparison measurement participation

Material costs		Amount in Eur
Direct material consumption		
Office articles	Correspondence	
PC operation costs	Printing current results; Printing partial reports; Printing final report	
Presentation	Presentation of results	
Other direct costs		
Depreciations from devices used	PC with accessories (3 %)	
Telephone	Telephone calls	
Mail connection	e-mail; mail costs	
Transport of measuring devices for input calibration		
Transport of measuring devices within MLPM		
Hire of measuring device		
Measuring device calibration (in reference laboratory)		
Special sponsor	Based on a contract	
Insurance		
Utilities costs (power, water, gas)	Included in administration costs	
Direct labour costs		
Indirect labour costs		
Total:		
Operation costs		
25 % of direct costs		
Administration costs		
15 % of direct costs		
Profit		
15 % of direct costs		
PRICE (without VAT)		
Number of participants		
Participant's fee		
