National Accreditation System

Policy for the use of proficiency testing, interlaboratory comparisons in accreditation and surveillance

NAR-03

3rd edition

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Introduction

According to Section 5.9 of ISO/IEC 17025:2005 and Section 5.6.3 of MSZ EN ISO 15189:2013 "Assuring the quality of testing and calibration results requires calibration and testing laboratories to have quality control procedures for monitoring the validity of tests and calibrations undertaken. The monitoring may include participation in interlaboratory comparisons or proficiency testing programmes, but also by other means, e.g, the regular use of certified reference materials or replicate tests/calibrations using the same or different methods. These methods provide a mechanism for a laboratory to demonstrate its competence to both its customers and the accreditation body."

National Accreditation Authority (hereinafter: NAH) policy for proficiency testing is in line with EA-3/04 [Use of Proficiency Testing as a Tool for Accreditation in Testing], ILAC P9:06/2014 [ILAC Policy for Participation in Proficiency Testing Activities] recommendations and directives.

NAH considers participation in interlaboratory comparisons (ILCs) and proficiency testing programmes (PTs) an important tool for demonstrating the technical competence of a laboratory. Therefore, in accordance with the recommendations and directives above this document sets out the policy of NAH for the use of proficiency testing, interlaboratory comparisons and the use of the results in accreditation and surveillance processes.

1. Definitions

For the purpose of this document, the definitions set out in MSZ EN ISO/IEC 17043:2010 are applicable.

1.1. **Proficiency Testing (PT)** is the determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body by means of interlaboratory comparison.

1.2. **Interlaboratory comparison (ILC)** is the organisation, performance and evaluation of calibrations/tests on the same or similar calibration/test items by two or more laboratories in accordance with predetermined conditions.

1. Policy

2.1. It is the policy of the NAH that all the accredited and applicant laboratories shall demonstrate technical competence. NAH gives great importance to the participation of laboratories in PT/ILCs, and considers the result of PT/ILC as one of the main tool for demonstrating their proficiency. The results of participation in PT/ILC are important part of the evaluation of laboratories during the assessment process.

2.2. Laboratories shall have policy for participation in PT/ILC. The laboratories shall study the availability of PT/ILC programmes and determine their suitability. When planning

participation in interlaboratory testing (PT/ILC) the laboratory shall check whether these have been organised in accordance with MSZ EN ISO/IEC 17043:2010. NAH recommends using services of the accredited providers, if available. The laboratories can be informed on NAH website too.

2.3. NAH informs the laboratories about the possibilities of participating in the interlaboratory comparison programmes that are organised as part of the activities of the EA or ILAC bodies. NAH appoints accredited laboratories to participate in these PT/ILCs on the basis of risk assessment. Participation of the appointed laboratories in the programme is mandatory. The participation may be refused only in special cases. If the laboratory refuses to participate, this can be a basis for suspension of that part of the accredited scope that uses the same technique or calibration covered by the programme. The results achieved in the PT/ILC schemes by the laboratories are monitored by NAH according to Section 3.

2.4. NAH recognises that there are particular test or measurement fields where PT/ILC is not practical or unreasonable. In such cases the laboratory shall present other reliable and effective tools for demonstrating its competence.

2.5. The policy of the laboratory and the frequency of participation in PT/ILC programs are subject to evaluation during the accreditation and surveillance procedure. The laboratory shall inform NAH on the PT/ILC programmes it participates in the application form for accreditation and scope extension.

2.6. The laboratories must organize the scheduled participations in the PT/ILC programs until the last surveillance. The laboratories shall provide the results of the PT/ILC programs.

2. General rules for participation in PT/ILCs

3.1. Laboratories that applied for accreditation are obliged, prior to obtaining the accredited status, to have a scheme for the participation in PT/ILC program, and participate in PT/ILC in the scope of accreditation. For the definition of the scope and frequency of PT/ILC is it suitable to take into consideration the EA-4/18 instructions (it can be downloaded from NAH website) (Table 1).

3.2. The recommended minimum participation of the accredited laboratories, in compliance with the documents of EA and ILAC, is once for each single discipline encompassed by the scope of accreditation, within the period of validity of the accreditation certificate (accreditation period: 5 years).

3.3. If the respective PT/ILC programmes are not available, the laboratory has to prove its competence in any other suitable manner (e.g. using certified reference materials, measurement audit, repeated testing/calibration, etc.).

3.4. The laboratory shall have procedures for the analysis of the results from the PT/ILC programme. If the results on PT/ILC was not acceptable, laboratories are required to have appropriate procedure for investigating flagged (or anomalous) results and carrying out appropriate corrective and preventive actions. The laboratories shall have appropriate

acceptance criteria and procedures for the treatment of coded (or misunderstandable) results and for corrective and preventive actions.

3.5. The laboratory is obliged to inform NAH in writing about participating and about the results of its participation in PT/ILC programmes. The report must contain the name and the identification of the programmes, the organizer's name, scope in which the laboratory participated, including the results and the organizer's evaluation on the competence for carrying out the tests, as well as corrective and preventive actions performed by the laboratory. The corrective and/or preventive actions are also monitored by NAH.

3.6. NAH does not organise PT/ILC programmes.

3.7. PT/ILC programmes may be organised by (among others):

- national accreditation bodies
- regulatory authorities (appointed reference laborator
- ies)
- commercial PT/ILC providers
- regional or international associations of accreditation bodies
- industry or producers' organisations or associations

A PT/ILC provider should function according to appropriate requirements (MSZ EN ISO/IEC 17043:2010). Accredited providers are preferred.

3.8. Mandatory participation can be requested due to standard requirement for testing or any other normative document, or due to requirements stipulated by the legislative regulation, professional, sectoral or interested parties.

3.9. When applying for annual surveillance laboratories are requested to inform NAH on the participation in PT/ILC programmes including:

- the name of the programmes and the date of its realization
- the name of the provider and its quality management system
- test item (material, matrix) and measurands (name of the measuring instruments) used
- criteria applied for the programme
- PT/ILC result for each characteristic/measurand
- results of PT/ILC analysis, and if necessary, preventive and corrective actions.

NAH may ask the participating laboratory to submit all documentation concerning the specific PT/ILC programme for evaluation. Laboratories are obliged to give explanations on their refusal to participate in available voluntary or mandatory PT/ILCs.

3.10. NAH makes available the national and international programs and contacts of the PT/ILC organizers on its website.

4. Specific rules for testing laboratories

4.1. When participating in voluntary PTs the laboratories shall take into account the following:

- PT/ILC covers the scope of accreditation in the highest possible percentage
- Test item (material, matrix) in the PT is (are) as close as possible to that routinely tested by the laboratory
- Measurands of test samples (materials) defined to determine the value of characteristic of sample (material) are as close to those routinely tested by the laboratory as possible
- The values of measurands are within the range in which the laboratory routinely performs tests of that type of samples
- Frequency of participation in PT is matched with the other means of control of tests used by the laboratory
- Statistical techniques/procedures used for the evaluation of PT results are appropriate to the measurands and test methods covered and the acceptance criteria for the results achieves are defined unambiguously.

4.2. In case when PT programmes are not available the laboratory shall organise interlaboratory comparisons with other laboratories on its own or participate in such comparisons. These comparisons may be conducted by two laboratories, but it is recommended to have more laboratories in order to provide more valuable results of comparison.

4.3. In the accreditation cycle testing laboratories shall participate with satisfactory results in at least one programme for each accredited main fields. In case of unsatisfactory results the laboratory shall repeat the test, measurement with satisfactory results in a PT/ILC in the field in the same accreditation cycle or plan to participations in PT/ILCs in the succeeding accreditation cycle.

4.4. Acceptance criteria for the results obtained used in the evaluation of laboratory performance is as follows:

- no result of any measurand can be unsatisfactory
- less than 20% of the results is questionable (e.g. using z score $2 < |z| < 3$)

4.5. Results of participation in PT/ILCs are taken into consideration by NAH when planning the scope of assessment of the surveillance visits.

4.6. NAH considers suspending the accredited status for part of the scope with tests or group of tests using the same techniques as in the PT/ILC programme in case of obtaining unsatisfactory results in two consecutive PT/ILCs.

5. Specific rules for calibration laboratories

5.1. In case of ILCs planned for calibration laboratories NAH takes into account the EA-2/14 M policy [Procedure for Regional Calibration ILCs In Support of the EA MLA].

5.2. Calibration laboratories, when applying for accreditation, are obliged to perform multilateral interlaboratory comparisons (ILC), or bilateral interlaboratory comparisons with reference laboratory before the initial assessment. (Table 1).

5.3. The Magyar Kereskedelmi Engedélyezési Hivatal (the Hungarian NMI) or accredited calibration laboratory having suitable best measurement capability can be used as reference laboratory. If no such reference laboratory can be found in Hungary, a foreign metrology institution or a laboratory accredited by EA MLA signatories can be used as reference laboratory.

5.4. In case the ILC results obtained by the laboratory are not satisfactory in accreditation process, the laboratory may perform corrective action and repeat the ILC. If the ILC results obtained in the second ILC are not satisfactory, the laboratory shall correct the scope of accreditation in the application accordingly.

5.5. In the accreditation cycle calibration laboratories shall participate with satisfactory results in at least one programme for each accredited calibration fields. ILCs may be performed as bilateral comparisons with reference laboratory or in the framework of available schemes. In case of unsatisfactory results the laboratory shall immediately inform NAH about corrective action taken. Effectiveness of corrective action taken shall be verified by participation in ILC covering the same scope of calibrations.

In case of unsatisfactory results, NAH may suspend the accredited status in the field. The conditions of resuming accreditation are notified to the laboratory together with the decision on suspending accreditation. In exceptional cases, after providing detailed explanations and justification on the results by calibration laboratory, NAH may agree that the laboratory participates in additional ILC programme.

5.6. Requirements (criteria) for evaluation of results obtained in ILC scheme are defined for each programmes by the provider. For the evaluation of ILC results against a reference laboratory, **En** numbers are used as defined in MSZ EN ISO/IEC 17043 standard.

5.7. Acceptance requirements (criteria) for the results obtained in the bilateral ILC used to evaluate calibration laboratory performance is as follows:

- no result can be unsatisfactory (i.e. |**En**| shall not be > 1).

5.8. Results of participation in ILCs are taken into consideration by NAH when planning the scope of assessment of the surveillance visits. NAH considers both the results obtained by the calibration laboratory and the way in which the results are used by the laboratory for improving its technical competence.

6. Specific rules for medical testing laboratories

6.1 The medical testing laboratories shall participate in interlaboratory comparison programmes suitable for their testing and test result assessments. The medical testing laboratories shall analyse the results of the interlaboratory comparison programmes and shall prepare corrective and preventive measures when the predefined performance criteria are not met and the cause-reason correlation is explored. (Table 1).

6.2. The medical testing laboratories shall prefer the services of proficiency testing providers accredited according to MSZ EN ISO/IEC 17043:2010 standard.

6.3. The medical testing laboratories shall develop a documented procedure according to 3.9.

6.4. The interlaboratory comparison programme(s) selected by the medical testing laboratories may be clinical tasks which ensure the control of the testing process on the basis of the testing of samples from patients, including pre-testing procedures and post-testing procedures, when they are available.

6.5. The participation of medical testing laboratories in interlaboratory comparison programmes is regulated by the Hungarian law with the taking into account of professional aspects. According to this, the medical testing laboratories shall participate in interlaboratory comparison programmes in national or international external quality control system at least four times a year, or at least twice if it is not available due to the specific services of the quality control provider.

6.6. Requirements (criteria) for the acceptance of the results used for the assessment of the operation of the laboratory are the following:

- Participation in the programmes min. 80 %;
- Uncertain (challengable) results less than 20% (e.g.: z result, $2 < |z| < 3$).

7. Specific rules for inspection organisations

7.1 Proficiency testing may be used for inspections where it is available and justified by the inspection activities directly affecting and determining the result of the inspection, or when it is required by the law or a regulatory authority. However, it shall be noted that proficiency testing is not a usual and expected part of the accreditation of most of the inspections.

7.2 NAH recommends the participation of the applicant / accredited inspection organisation in suitable PT activities in case they are available and/ or relevant. NAH publishes the PT programs on its website.

7.3 In case of critical inspection and calibration activity the recommended minimum number of proper PT activities is at least 1 per main activity before the application for accreditation is submitted. If there are a relevant and available PT programs every accredited inspection organisation shall participate in those at least once a year. During the accreditation cycle further participation is recommended in the individual accreditation scopes. The law or industry specific requirements may specify otherwise.

7.4 The inspection organisations shall prepare a plan to prove their competence. It may be external or internal. The results of the compulsory inspections may also be used.

7.5 In case the inspection organisations participate in PT programmes, the provisions of Sections 1-4 are governing.

7.6 The inspection organisations performing analytic or non-destructive testing should participate in proficiency testing programs (in case the result of the measurement/testing has a great impact on the result of the inspection), but the reliability, authenticity of the measurement may be proven otherwise (see Section 5.9 of MSZ EN ISO/IEC 17025:2005 standard), or by the certified qulification of the inspector.

7.7 Due to the specific nature of the activities of the inspection organisations the participation in external proficiency testing is often difficult. The inspection organisations may demonstrate their competence via other comparisons (within or outside the organisation). Depending on the dimensions of the inspection service provision and the performance expectation of the inspectors the following possibilities are available:

a) Comparison of inspection findings

One or more inspection organisations (at the same time or in a given time interval, if the stability is ensured by the inspected item) may perform inspection for the purpose of comparison. The results of the inspection may be evaluated by numeric, qualitative or statistical analysis. The participants agree on the acceptance by mutual consensus.

b) Measurement inspection (measurement audit)

The measurement audit may be used similarly to evaluate the performance. The reliability of the measurement may be concluded from the difference (qualitative or quantitative characteristics) between the inspection (measurement) result and a known reference value.

c) Monitoring the inspection activity

An inspector may be monitored by another inspector during the inspection activity to confirm that the inspection activity is performed in compliance with the professional rules, the inspector is competent in the scope of accreditation. This technique is often used to check the efficiency of training. ILAC P15 requires that during performance inspection the inspection cover the witness audits with the involvement of the professionally competent staff and the selection of representative samples.

d) Surveillance of inspection reports, notes and documents

In some cases the checking of reports and notes, the surveillance of the register may be sufficient to determine whether the site inspections were performed properly (e.g. condition inspection of structures, where there are a lot of photographs, original observations, notes, drawings, etc are available).

7.8 The participation in PT inspection programs may be an effective method to prove the inspection competence of the staff, to evaluate the performance of the organisation, and to support the reliability of their approved procedures.

WORKPLAN
for the participation in PT/ILC-ben
according to NAR-03

Table 1

Year	**Matrix / measured components / instrument to be calibrated**	**Name and quality control system of organiser**	**Name of cooperating testing or calibration laboratory**	**Planned date**	**Implementation date**	**Result**	**Root cause analysis / Identification of corrective / preventive measure**	**NAH measure**
Year 1								
Year 2								
Year 3								
Year 4								

8. Closing provisions

8.1 The general director of the NAA issued this rule in the 21/2016 Director-General's order.

8.2 Present rules enter into force on 22 August 2016.

8.3 Present rules are applicable for the ongoing matters.

8.4 The publication of present rules on the website of NAH (www.nav.gov.hu) is considered publication.

8.5 The questions not regulated herein are governed by the provisions of Act CXXIV of 2015. In case Act CXXIV of 2015 does not specify a specific provision, the provisions of Act CXL of 2004 are governing.