

1. INTRODUCTION

One of the services provided by NBE is to assess and accredit the competence of proficiency testing providers. This guideline lays down the applicable rules and standards that must be observed during the accreditation of proficiency testing providers. This guideline is issued to benefit the relevant parties considering the experience derived from NBE's assessment processes and knowledge built in international efforts.

This guideline is applicable to the accreditation of proficiency testing providers which organize interlaboratory comparison for the purposes of proficiency testing in order to measure and monitor the performance of laboratories.

The purpose of the assessment is to check the compliance of proficiency testing providers with the requirements of ISO/IEC 17043 standard, EA and ILAC documents and NBE guidelines. NBE employs technical assessors and experts with specialist knowledge in the subject matter to assess the competence of proficiency testing providers seeking accreditation. The confidentiality of information obtained by assessors and experts during the assessment is ensured by forms and contracts prepared by NBE in respect of ethical rules.

This guideline introduces additional requirements to the assessment processes conducted according to Procedure for the Accreditation of Conformity Assessment Bodies (PR-7-01).

2. DEFINITIONS

2.1. Interlaboratory Comparison (ILC): Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

2.2. Proficiency Testing (PT): Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

2.3. Proficiency Testing Scheme: Proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection.

2.4. Proficiency Testing Round: Single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants.

2.5. Proficiency Testing Provider: Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.

3. RELEVANT DOCUMENTS

3.1. ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing

3.2. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

3.3. ISO 15189 Medical laboratories – Requirements for quality and competence

3.4. ISO 17034 General requirements for the competence of reference material producers

3.5. ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparison

3.6. ILAC P13 Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers

- 3.7.** EA 2/18 Guidelines for accreditation bodies on the contents of the scopes of accreditation for proficiency testing providers
- 3.8.** G-1-06 Requirements for Using NBE Accreditation Symbol by the Accredited Bodies
- 3.9.** FR-7-01-103 Laboratory Accreditation Department Information Declaration Form
- 3.10.** PR-7-04 The Procedure for Proficiency Tests and Interlaboratory Comparison Programs

4. APPLICATION

A proficiency testing provider which files an application for accreditation shall submit information to the NBE on its activities; Proficiency Testing Field; Tested Materials / Products; Name of the Proficiency Testing Scheme / Test Type / Measured Parameter; Frequency of Program; Proficiency Testing Method / Procedure / Techniques; organizational structure and subcontractors.

A proficiency testing provider which files an application for accreditation completes its application by transmitting the completed Application Form for Accreditation for Proficiency Testing Providers (FR-7-01-74) and annexes to NBE. The documents indicated in The Requested Documents for Proficiency Testing Providers (FR-7-01-73) at Application According to ISO/IEC 17043 and Laboratory Accreditation Department Information Declaration Form (FR-7-01-103) shall be sent to in the relevant section of NBE e-mail.

In the application for initial accreditation, the proficiency testing provider must have organized and completed at least one proficiency testing scheme in each of the scopes to which the proficiency testing provider applies. If there is an incomplete proficiency testing scheme similar to the completed proficiency testing scheme requested for accreditation, NBE may decide to include the incomplete proficiency testing scheme within the scope of the accreditation assessment after carrying out the necessary examinations.

The accreditation assessment of a proficiency testing provider is performed by document review, on-site assessment by visiting the head office and branch offices if any, and supervising the assessment of subcontractors by proficiency testing provider in the context of the relevant activity as required.

This document lays down how NBE shall plan and perform initial assessments, surveillance assessments and re-accreditation assessments through an accreditation cycle for proficiency testing providers serving according to the requirements of ISO/IEC 17043 standard.

5. REQUIREMENTS FOR ACCREDITATION OF PROFICIENCY TESTING PROVIDERS

Proficiency testing providers are expected to meet the following additional requirements in relation to ISO/IEC 17043 standard.

5.1 Personnel

5.1.1. Additional requirements must be defined for the qualifications required to select and assign the proficiency testing scheme coordinator; authorized personnel who shall make the statistical design; quality manager, technical manager and advisory group.

5.1.2. Where an advisory group or technical experts are assigned and additional expertise is required, the proficiency testing provider is advised to prepare the list of experts and

documents containing technical knowledge of experts in addition to which fields of proficiency testing they are assigned.

- 5.1.3.** Where an advisory group is assigned, its working principles and procedures must be defined.

5.2 Devices, layout and environmental requirements

The proficiency testing provider must comply with the rules if any established by the national or local regulator.

5.3 Reports

- 5.3.1.** In the reports of proficiency tests outside the scope of accreditation, the proficiency testing provider must use language to that effect; i.e. not in its scope of accreditation.
- 5.3.2.** The proficiency testing provider shall develop methods to clearly distinguish between accredited scopes and non-accredited scopes in its proficiency testing reports. It is necessary to pay attention to the issues stated in the Requirements for Using NBE Accreditation Symbol by the Accredited Bodies (G-1-06)

5.4 Organization

Where the laboratory of the proficiency testing provider is a participant in the proficiency testing organized by the proficiency testing provider; there must be documented procedures in place to prevent falsification or manipulation of the results. The personnel involved in the proficiency testing scheme activities must be different than the personnel participating in the proficiency testing scheme (if applicable), and this must be documented.

5.5 Subcontracted Services

- 5.5.1.** Proficiency testing providers can benefit from subcontractors in activities such preparation of test items, homogeneity, stability, determination of assigned value, etc. for the operation of proficiency testing schemes. During the assessment, the lead assessor and assessor/technical expert shall evaluate convenience of the records kept by the PT provider regarding the competence of subcontractor laboratories performing tests or measurements related to the proficiency testing scheme in accordance with the requirements of ISO/IEC 17025 or ISO 15189 standards. Subcontractor shall demonstrate its competence by participating in proficiency test or interlaboratory comparisons in accordance with the criteria specified in "PR-7-04 Procedure for Proficiency Testing and Inter-Laboratory Comparison Schemes". Such records shall be recorded and presented during the assessment to NBE assessment teams by PT provider.
- 5.5.2.** The proficiency testing provider shall ensure the competence of any subcontractor. The fact that the subcontractor is accredited may demonstrate its competence in the relevant field of activity. If possible, accreditation should cover all services of the subcontractor. In any case, the PT provider who subcontracts work must ensure that the subcontractor is sufficient for the work to be performed. This assurance may be provided by an assessment in the subcontractor laboratory or by other procedures developed by the PT provider.

- 5.5.3.** There must be a binding contract between the proficiency testing provider and the subcontractor indicating, as a minimum, the responsibilities of the subcontractor, possibility that the proficiency testing provider may conduct an assessment, the possibility of NBE to supervise the assessment of the subcontractor by proficiency testing provider, and confidentiality policy.
- 5.5.4.** If the PT provider uses a subcontractor laboratory, all the information, documents, records and documents related to subcontractor evaluation should be sent the NBE e-mail before the assessment.
- 5.5.5.** Where the proficiency testing provider uses a subcontractor; it is recommended to have periodical visits to ensure that appropriate preparation of proficiency test items, appropriate environmental conditions etc. are met.
- 5.5.6.** The confidentiality of identities of proficiency testing scheme participants must be protected in the activities subcontracted to a subcontractor.
- 5.5.7.** Where such critical services as homogeneity and stability are subcontracted to a subcontractor; it should be possible, during the accreditation assessment, to present to the assessment team all technical records, statistical calculations of subcontractor's activities including particularly homogeneity and stability.
- 5.5.8.** It is essential that traceability be ensured for services subcontracted to a subcontractor.
- 5.5.9.** If PT providers and the laboratory are under the same organization, it is not considered as subcontractors.

5.6 Internal audit

Where the proficiency testing provider uses a subcontractor; the subcontracted activities may be included in the internal audit. The audit of subcontracted activities may preferably involve on-site visit to the subcontractor when it is conducting such activities. It is recommended that a competent internal auditor witness the subcontractor activities periodically. Such audits must be recorded and presented during the assessment to NBE assessment teams.

6. ASSESSMENT PROCESS

NBE shall confirm which branch offices perform proficiency testing services and which of them perform key activities. Key activities usually include such processes that influence the competence of a CAB, e.g. policy formulation; development of process and/or procedure including the design of proficiency testing schemes and contract review where appropriate; planning the conformity assessment activities; reviewing the results of conformity assessment activities, endorsement and decisions relating thereto; monitoring the competence of technical personnel and subcontractors; data analysis; evaluation and reporting of proficiency testing results.

The proficiency testing provider must notify to NBE prior to the assessment which personnel are competent for which activities in which fields (i.e. the competence matrix).

Proficiency testing providers can use internal laboratory in activities such preparation of test item, homogeneity, stability, determination of assigned value, etc. for the operation of proficiency testing schemes. During the assessment, the lead assessor and assessor/technical expert shall

assess compliance of the activities of the internal laboratory performing tests or measurements according to the requirements of ISO/IEC 17025 or ISO 15189 standards. Accreditation of internal laboratory in accordance with ISO/IEC 17025 or ISO 15189 demonstrate its competence in the relevant field of activity, it does not need to be assessed again. However, if the internal laboratory is not accredited according to ISO/IEC 17025 or ISO 15189, the standard requirements will be verified by the assessment team members and the competence of the laboratory will be assessed in the relevant scope during the assessment. As a result of this assessment, it should not be deduced that the internal laboratory is accredited with ISO/IEC 17025 or ISO 15189 standards. Internal laboratory shall demonstrate its competence by participating in proficiency tests or interlaboratory comparisons in accordance with the criteria specified in Procedure for Proficiency Testing and Inter-Laboratory Comparison Schemes (PR-7-04).

The critical activities performed by a subcontractor may be observed by NBE during the accreditation assessment. In the contract signed by the CAB with the subcontractor, the issue regarding NBE's ability to visit the subcontractor on-site should be included and this issue should be guaranteed.

Contract with the subcontractor should be sent by CAB the NBE e-mail. Where the assessment team determines that the subcontractor of a proficiency testing provider fails to meet the requirements, it may propose a suspension of accreditation.

The activities and locations to be assessed are selected by taking into account the risks in CAB's accreditation scope and/or sampling of the locations where it operates. In this case, before conducting the assessment, it is important to select as many and various activities and locations as necessary to prove technical competency in the relevant scope.

Schemes under each reported field in the scope shall be subject to assessment. A representative sampling may be drawn to demonstrate the competence of a proficiency testing provider. When drawing a sample, the assessment team must consider the following, though not to be limited to these rules:

- Diversity and choice of schemes considering the type of testing/calibration properties,
- Monitoring a maximum number of technical personnel assigned to specific activities.

Furthermore, when sampling, the frequency of scheme, the experience of the proficiency testing providers, the experience of the personnel conducting the test, the findings of the previous assessment should be taken into account.

The assessment team must make the following record entries during assessments in accordance with Assessment Team Working Instructions (I-7-01-13):

- The persons interviewed during the assessment be recorded in Participants List of Assessment (FR-7-01-36),
- The documents and records reviewed during the assessment be recorded in List of Reviewed Documents and Records During the Assessment (FR-7-01-45),
- The assessment team may use Checklist for Proficiency Testing / Inter Laboratory Comparison Scheme Providers (FR-7-01-75).

7. SURVEILLANCE ASSESSMENT AND RE-ASSESSMENT

An accreditation cycle program is prepared for each CAB that will enable assessment in related locations in a way to represent all activities in the scope of accreditation (scope in the annex to the accreditation certificate) together with the management system throughout the cycle in accordance with Procedure for the Accreditation of Conformity Assessment Bodies (PR-7-01). Changes in the management system and organization shall be reviewed within the framework of a risk-based approach. Depending on the significance of changes, the number of assessment days may be increased.

When planning assessments within the accreditation cycle of PT providers, the risk factors to consider may include, but are not limited to the following:

- Personnel changes,
- The changes in equipment used in proficiency testing,
- Changes in locations,
- Nonconformity identified in the previous assessment, observation and/or scopes to examine proposed by the assessment team,
- Changes in subcontractor use and subcontractor information,
- Revised standards, internal methods, etc. within CAB's scope,
- Changes in legal authority, regulations, legislation requirements,
- Corrective/Preventive actions performed by CAB for non-conforming work,
- The frequency of conformity assessment activities performed within the scope of accreditation and the number of reports they produce,
- Feedback or complaints received from the relevant parties.

Re-assessments shall be conducted in form and content similar to the initial assessment to include a comprehensive re-assessment of the activities and quality system of proficiency testing providers.

8. SCOPE EXTENSION

Where possible, the assessments relating to the scope extension request of the body shall be conducted in conjunction with surveillance assessments or re-assessment. Where necessary, a follow-up assessment may be organized.

When an accredited proficiency testing provider applies for scope extension for proficiency testing scheme similar to the scope to which it is accredited, NBE may decide to carry out an assessment and to include the incomplete proficiency testing scheme in the accreditation scope. However, in order to extend the scope from a new area by the proficiency testing provider, the proficiency testing scheme must be completed.

Scope extension in the proficiency testing area may be treated as a new scheme, new properties, new proficiency test items or new location.

9. CONTENTS OF THE SCOPES

An example of the scope for proficiency testing providers is provided in TABLE 1.

PROFICIENCY TESTING FIELD - TESTED MATERIALS / PRODUCTS	NAME OF THE PROFICIENCY TESTING SCHEME / TEST TYPE / MEASURED PARAMETER	PROFICIENCY TESTING METHOD / PROCEDURE / TECHNIQUES	FREQUENCY OF PROGRAM
Construction materials- Natural stone	Natural stone test methods - Determination of the slip resistance by means of the pendulum tester / simultaneous / Sliding Resistance Value (SRV)	EN 14231 Natural stone test methods - Determination of the slip resistance by means of the pendulum tester	Once a year
Gasoline	Determination of Lead	Proficiency Testing Implementation Procedure (PR-XX)	2 times/year
Waste oil	Determination of flash point/ simultaneous / flash point	Proficiency Testing Implementation Technique (I-XX)	2 times/year
Water	Determination of Heavy Metals (Aluminium (Al), Arsenic (Ar), Copper (Cu), Zinc (Zn))	Proficiency Testing Implementation Procedure (PR-XX)	2 times/year

- TABLE-1. Example Scope for Proficiency Testing Providers -