

## **1. PURPOSE**

The purpose of this procedure is to define the conditions concerning proficiency tests and interlaboratory comparisons, which should be attended by laboratories which desire to be accredited by NBE or which desire to sustain their accreditation statuses and, when necessary, by inspection bodies.

## **2. SCOPE**

This procedure includes the activities of the testing/calibration and medical laboratories, which desire to be accredited and sustain its accreditation, and, when necessary, of the inspection bodies, concerning the relevant proficiency test and interlaboratory comparisons, the assessment of the assessment team concerning these activities and evaluation of NBE concerning these activities.

This procedure also includes External Quality Assessment (EQA) activities for the medical laboratories that meet the requirements of proficiency testing.

Hereinafter, instead of testing, calibration and medical laboratories and inspection bodies, the term “laboratories” will be used.

## **3. DEFINITIONS**

The definitions related to this procedure are given in the documents, Instructions of Definitions and Abbreviations used in I-5-01-4 NBE Documentation and EA-4/18 Guidance on the level and frequency of proficiency testing participation.

## **4. RELATED DOCUMENTS**

- 4.1.** ISO/IEC 17043: Conformity assessment – General Requirements for proficiency testing
- 4.2.** ISO/IEC 17011: Conformity assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
- 4.3.** ISO /IEC 17025: General Requirements for the Competence of Testing and Calibration Laboratories
- 4.4.** ISO 15189: Medical Laboratories – Particular Requirements for Quality and Competence
- 4.5.** ISO/IEC 17020 Requirements for the operation of various types of bodies performing inspection
- 4.6.** ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities
- 4.7.** ILAC P13: Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers
- 4.8.** ILAC P15: Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- 4.9.** EA 4/18: Guidance on the Level and Frequency of Proficiency Testing Participation

**4.10.** EA 2/18: Guidelines for Accreditation Bodies on the Contents of the Scopes of Accreditation for Proficiency Testing Providers

**4.11.** EA 4/21: Guidelines for the Assessment of the Appropriateness of Small Interlaboratory Comparison within the Process of Laboratory Accreditation

**4.12.** FR-7-04-1: Proficiency Testing and Interlaboratory Comparisons Participation List

## **5. APPLICATION**

### **5.1 NBE Policy and Principles for Proficiency Tests and Interlaboratory Comparison Programs**

The laboratories that desire to be accredited by NBE and those that desire to sustain the accreditation granted are responsible for conducting the necessary activities for proving their technical competencies and to monitor this competency. One way to prove the technical competency is the participation of the laboratories in the proficiency tests in the available and appropriate cases and to obtain successful results. Other ways may include the regular use of reference materials and repeating the tests or calibrations using the same or different methods.

Technical competency may also be demonstrated by participating in the interlaboratory comparison programs, which are not organized as proficiency tests, and by obtaining successful results. The following may be given as examples of these programs:

- Evaluation of the performance characteristics of a method,
- Determination of the properties of a reference material,
- Comparison of two or more laboratories results on their own initiative,
- Demonstration of equivalence statement of National Metrology Bodies measurements

Proficiency tests and interlaboratory comparison programs should meet the conditions of ISO/IEC 17043 standard.

### **5.2 NBE Criteria for Proficiency Tests and Interlaboratory Comparison Programs**

Proficiency Tests and interlaboratory comparison activities are important tools for demonstrating the competency of the laboratories and to contribute to maintain the quality of their activities. The laboratories may also use the proficiency tests or interlaboratory comparisons as a laboratory education and risk management tool. NBE desires that the laboratories applying for accreditation realize activities according to the below mentioned criteria concerning proficiency tests and interlaboratory comparisons.

#### **5.2.1 Accreditation Process**

During the accreditation application of the laboratories to NBE, their minimum activities concerning their participation in Proficiency Tests or Interlaboratory Comparisons shall be as follows.

- a) When the proficiency test or interlaboratory comparison program is available and appropriate, obtained successful result/results before the granting of the Accreditation should be presented, with its proofs annexed, by filling in the Proficiency Testing and Interlaboratory Comparisons Participation List (FR-7-04-1). For granting accreditation, at least one successful result shall be obtained.
- b) Sub-fields concerning the applied accreditation scope should be determined and proficiency tests or interlaboratory comparison programs participation plan prepared in consistency with these sub-fields should be prepared by using Proficiency Testing and Interlaboratory Comparisons Participation List (FR-7-04-1) and the records of the activities realized concerning this plan should be presented.

NBE examines the conformity of the proficiency tests or interlaboratory comparison programs participation plans presented concerning the Accreditation scopes. In cases where proficiency tests or interlaboratory comparison programs are not available or where participation is not possible, NBE and the laboratory should discuss the subject and come to an agreement concerning the alternative appropriate ways, through which the competency can be evaluated and monitored. This situation will be considered as a part of the proficiency tests or interlaboratory comparison programs participation activities plan.

It is expected from the laboratories to participate proficiency tests on different measurement intervals, where appropriate, for each participation. Throughout the period when the laboratories sustain the accreditation, laboratories should notify all the results they obtain from the proficiency tests or interlaboratory comparisons to NBE; and they should notify the activities they conduct concerning unsuccessful results, the records concerning this activity and the participation plans they update to NBE.

### **5.2.2 Proficiency Tests and Interlaboratory Comparison Programs Participation Plan**

The participation plan provides the laboratories with the opportunity to analyze their needs and to determine the appropriate participation level and frequency. The laboratories should prepare a “Proficiency Tests and Comparison Measurements Participation Plan”, which is consistent with their Accreditation scope and which contains the sub-disciplines within the scope and their participation level and frequency; and they should update this plan according to the conditions affecting the competency. EA-4/18: Guidance on the Level and Frequency of Proficiency Testing Participation document should be utilized for the determination of the sub-fields. Participation level and frequency in the proficiency tests or interlaboratory comparisons should be considered in relation with risk level concerning the test or calibration activities of the laboratory. Sub-fields should be determined by laboratories in a way that all methods and matrices included in the scope of accreditation shall be represented and participation in different parameters in the determined sub-fields should be ensured.

The consistency of the sample type, given in the participation plan, with the sample type utilized mostly by the laboratory in its daily activities should be considered. In this regard;

- a) In cases such as personnel, method and equipment changes, the participation plan should be reviewed regularly and should be updated according the need.
- b) The participation plan should be reviewed according to the performance obtained in the proficiency test or interlaboratory comparisons (especially in cases where unsuccessful results are obtained continuously) and, when necessary, it should be updated.

The laboratories shall be participated proficiency tests at least once every 48 months for each identified sub-field and obtained successful results. The suitability of the participation plans prepared by the laboratories shall be evaluated by the assessment teams in the assessments.

### **5.3 Evaluation of the Results**

During the assessments, the assessment teams, appointed by NBE, evaluate the participation plans of the laboratories and the results they obtained from their participations within the framework of the criteria in question; and they come to a judgment concerning the technical competency of the laboratory. In cases where unsatisfactory results are obtained, they examine the efficiencies of the corrective actions and, if necessary, they might request additional corrective actions. Out of the limit scores  $|z|$ ,  $|z'|$  and  $|\text{zeta}| \leq 2.0$  and  $|En| \leq 1$ , those scores are evaluated as unsatisfactory results, it is expected to initiate a corrective action and / or to ensure that the situation is under control. In cases where the assessment team is not sure about the technical competency of the laboratory, it might request the participation of the laboratory in the proficiency test and interlaboratory comparison in the related field.

Apart from the assessments, NBE evaluates, when necessary, the efficiency of the corrective actions realized by the laboratories concerning the unsuccessful results (proficiency test or interlaboratory comparisons), that they declared to NBE, with the support of the relevant experts and, if necessary, NBE updates the Accreditation decision of the laboratory according to the new situation.

Within the accreditation decision process, the proficiency tests and interlaboratory comparisons participation plans of the laboratories, their participations and the results they obtained are examined and evaluated. If unsuccessful results of the laboratories are available, the relevant corrective actions they realized are examined and evaluated. In cases where the laboratories obtain constantly successful results, options such as applying different monitoring intervals might be practiced.

### **5.4 Types of Interlaboratory Comparisons and Proficiency Tests**

participation obligatory. In these cases, when appropriate, NBE provides guidance to the laboratories that it accredited. NBE does not organise proficiency tests or interlaboratory comparisons.

Interlaboratory comparisons or proficiency tests might be organized by Independent Bodies, ILAC or laboratories among themselves.

Where requested by NBE, participation to proficiency tests/ interlaboratory comparison schemes organized by ILAC or other schemes designated by NBE is mandatory.

Primarily, laboratories should select programs of proficiency testing providers operating at national and / or international levels and accredited in accordance with ISO / IEC 17043 standard. If such programs are not available, proficiency testing programs organized by providers meeting the requirements of ISO / IEC 17043 standard should be preferred.

In cases where the above mentioned programs are not available and application of alternative quality control methods is not possible, the laboratories might tend to programs organized by laboratories among themselves. Such programs should also meet the requirements of ISO / IEC 17043 standard.

The laboratories should submit evidence to NBE assessment team that the participated proficiency testing programs meet the requirements of ISO / IEC 17043 standard. If the assessment team evaluate the presented evidence is not fulfilling the requirements of T ISO / IEC 17043 standard, the laboratory should participate in a new proficiency test or interlaboratory comparison program.

#### **5.4.1 Programs Organized by Independent Bodies**

The participant laboratory is responsible for the compliance of the proficiency test and comparison program, offered by the organizer body, with the ISO/IEC 17043 standard. Laboratories should follow up the relevant organizations.

There is an EPTIS (European Proficiency Testing Information System) database which contains/provides information of international proficiency testing programs. Participant laboratories should select the appropriate proficiency testing program.

It is expected from laboratories to follow up other national and international organizations.

#### **5.4.2 Programs Organized by Laboratories among Themselves**

Since limited number of participants are available in these kinds of comparison programs, the statistical evaluations conducted might not be sufficient. These kinds of programs might be accepted by force of the relevant policy in cases where the above mentioned programs are not available and application of alternative quality control methods is not possible.

### **6. AUTHORITY AND RESPONSIBILITIES**

Testing Accreditation Department, Calibration Accreditation Department and Product, Service and Inspection Accreditation Department are responsible for the execution of this procedure.

### **7 ARCHIVE AND RECORDS**

All records are kept in accordance with the Procedure on Control of the Records (PR-5-02).

**REVISION HISTORY:**

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