WEST AFRICAN ACCREDITATION SYSTEM (SOAC)

PARTICIPATION IN PROFICIENCY TESTING ACTIVITIES (C10.01)

Approval		Effective Date
Date	01/11/19	01/11/19

SUMMARY

1 PURPOSE AND SCOPE

This document is intended to be used by laboratories to monitor the validity of tests and calibrations undertaken. The requirements for **participation in proficiency testing programmes (PTP)** are indirectly also applied to inspection bodies and certification bodies in relation to tests or calibrations which they conduct within their accredited procedures of inspection or certification.

2 REFERENCES

- ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities
- ISO/IEC 17020, Conformity assessment — Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17043, Conformity assessment — General requirements for proficiency testing
- EA-4/18, Guidance on the level and frequency of proficiency testing participation.
- EA-4/21 INF, Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

3 EFFECTIVE DATE AND REVIEW

This document is applicable from the date specified on the cover page. It will be updated as necessary.

4 SUMMARY OF CHANGES

Version 00: creation.
Version 01: revision and update for some new dispositions addressed.

5 TERMS AND DEFINITIONS

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

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

6 REQUIREMENTS

6.1 Participation in appropriate proficiency testing, when available, is one of the conditions for a laboratory to obtain and maintain accreditation. When a laboratory needs to assure confidence in its results, it must regularly and to an appropriate extent take part in proficiency testing. In this context, the laboratory

must have its policy stated, its plans made, and its procedures for processing the results and implementing the necessary action in place.

6.2 Before accreditation is granted, applicant laboratories and inspection bodies when applicable shall demonstrate successful participation in **at least one relevant and available** proficiency testing activity. It is recognised that there are areas of testing and calibration for which suitable proficiency testing does not exist or is not practical. In such cases, SOAC and the laboratory shall discuss and agree on suitable alternative means by which performance can be assessed and monitored (e.g. when the laboratory has demonstrated competency through internal performance-based data). This would need to be considered as part of the planned PT and/or related activities.

6.3 Proficiency testing differs by their purpose, organisation, number of participants, etc. It is important for a laboratory to choose adequately, in compliance with its needs, and to make sure about the suitability of organisation, implementation, and evaluation of the results. Also in the case of comparison of results between laboratories, these should try to meet as much as possible the requirements of ISO/IEC 17043.

6.4 In line with the ILAC (ILAC P9) policy, SOAC will require a laboratory's participation in interlaboratory comparisons **at least once before the grant of accreditation**, and subsequently, at least once during the period between reassessment visits (**02 years**) in each of the larger sub-areas within the laboratory's scope of accreditation.

6.5 All accredited laboratories shall participate in **relevant** and **available** proficiency testing at a **frequency sufficient** to ensure that **all activities of the scope(s) of accreditation are covered over a 02 year period.** A laboratory shall plan the scope of its participation in ILCs in accordance with its accredited activities (capacity).

6.6 The requirement under 6.5 concerning the frequency of participation is a minimum requirement. Many areas require much more frequent participation, whereas in other cases, for lack of organised comparisons, even this minimum requirement cannot be met. It is important, however, that **the frequency of participation in interlaboratory comparisons is aligned with the scope of use of other means of assuring the quality of testing and calibration**. (Less frequent participation in interlaboratory comparisons, for example, may require more: equipment calibration, use of reference materials, repeated testing, control, and vice versa).

6.7 Under special circumstances (important changes in the laboratory, nonconformities found, extra critical tests or calibrations), SOAC **may require the laboratory's participation in interlaboratory comparisons in shorter intervals.**

6.8 In order to attain the purpose of participation as a means of quality assurance**, the laboratory needs to introduce procedures for examining the results,**

following the trends, deriving findings, as well as implementing and reviewing corrective actions. All these activities must be properly documented.

7 ASSESSMENT

7.1 The suitability of the scope of participation and the adequacy of chosen proficiency testing **shall be estimated by the assessment team during the assessment procedure.** Both the actual possibilities and situations in the relevant area should be taken into account.

Possibilities of participation in interlaboratory comparisons differ greatly in different areas. Laboratories should choose such comparisons that meet the requirements of international standards. **In the absence of proficiency testing** organised by third parties, even comparisons between two or more than two laboratories, organised by the laboratories themselves, are welcome.

7.2 When assessing the proficiency testing results, provided by a PT provider, who operates in accordance with ISO/IEC 17043, the focus is mainly on the **performance obtained by the laboratory** and **the criteria used** by the PT provider to establish the evaluation of performance**.**

But when assessing the results from a small ILC, the operation of the small ILC is to be assessed in order to check that they have been organised in agreement with the relevant requirements of ISO/IEC 17043.

The assessment depends on which of the following two situations are encountered when assessing a laboratory in relation to a small ILC:

- **The laboratory assessed has organised and participated in the small ILC.**

In this situation, the assessor will evaluate the plan (Annex A) and report (Annex B) along with the organisation of the small ILC to conclude upon its relevancy, according to relevant requirements of ISO/IEC 17043.

- **The laboratory assessed has only participated in the small ILC.**

In this case, the laboratory should be able to provide details to the assessor on how they have evaluated and decided on the fitness for purpose of the small ILC. The assessor should evaluate these details, taking into account the relevant requirements of ISO/IEC 17043, in order to conclude upon the relevancy of the small ILC.

Any unsatisfactory results that are obtained from participation in a small ILC are to be treated by the laboratory, like all the other unsatisfactory ILC results, as non-conforming work (see ISO/IEC 17025 and ISO 15189) and the actions were taken are to be specifically assessed. The criteria used for the evaluation of performance should be fit for purpose.

7.3 **The plan, the results, the analysis,** as well as any possible actions deriving from the result of participation in ILCs, shall in accordance with the accreditation procedure constitute **an obligatory part to review during each assessment visit.**

When applying, and before each visit, the laboratory shall transmit to SOAC its proficiency testing/interlaboratory comparisons participation plan and its results.

The plan shall be reviewed and updated, as necessary, as part of the laboratory's management review.

7.4 When a laboratory's participation is unsuccessful, and the appropriate action has not been taken in proper time, or when a laboratory has unsuccessfully participated several times in a sequence, SOAC may require another participation in a similar comparison; undertake an extraordinary assessment, or withdraw partly or completely the laboratory's accreditation.

8 TABLE OF MODIFICATIONS

No.	Source	Modification in brief (Relevant changes)
C10.00- 28 June 2019		
Creation		
C10.01- 12 September 2019		
1	§ 1	Terminology ‘’participation in interlaboratory comparisons (ILC) has been replaced by ‘’participation in proficiency testing programmes’’ (PTP) in this section.
2	§ 2	References have been revised in line with the wording of the standards and updated : 2 references withdrawn (ISO/IEC 17011; ISO/IEC 13528) and 3 references added, ISO/IEC 17043, ISO/IEC 17025 and ISO/IEC 17020
3	§ 3	The title has been revised
4	§ 5	Definition of ILC revised in line with the one given in ILAC P9
5	§ 6.1 ; § 6.3 ; § 7.1 ;	The word ‘’proficiency testing’’ used in these following sections to replace the word ‘interlaboratory comparison’’
6	§ 6.2	This section has been technically revised and some words removed while others added to give some specific examples
7	§ 6.3	Some words removed to clarify the requirement of ISO/IEC 17043
8	§ 6.5	This section has been technically revised
9	§ 6.6	§ 6.4 cited in this section changed to § 6.5
10	§ 6.8 and 6.10	These 2 sections have been withdrawn. And § 6.9 became § 6.8
11	§ 7.1	This section has been technically revised and some words removed
12	§ 7.2	§ 7.2 changed to § 7.3 and a new section created. These two

No.	Source	Modification in brief (Relevant changes)
		sections have been technically revised and some word removed to provide detailed information on the assessment in general
13	§ 7.3	This section has been technically revised
14	§ 7.4	The expression ‘’surveillance visit’’ has been removed.
15	Annex A	This section added to address the planning of the small ILC
16	Annex B	This section added to address reports of the small ILC

Annex A: Planning of the small ILC

The planning of the small ILC is the main focus point of the assessment of the small ILCs. The plan shall include a detailed description of the operation of the small ILC. these following points should be included or elaborated in the plan:

- Main contact person
- If organised jointly, the persons or laboratories involved
- List of participants
- The measurand or characteristic to be determined
- Requirements (production, homogeneity, stability) for the ILC test item
- Information on the use and preparation of the ILC test item (description of the preparation, if applicable)
- The timeframe of the scheme
- Information on the method(s) to be used
- Description of the method for the evaluation of the comparability of the results, statistical analysis, if applicable, and the criteria used for the evaluation of performance
- Description of the reporting format for the participants and from the organiser

Annex B: Reports of the small ILC

A report should be established by the ILC organiser. As a minimum, the following points should be included in the report:

- Date of small ILC
- Contact person
- Persons or laboratories involved in the organisation of the small ILC
- Identification of the small ILC scheme
- Description of the small ILC item
- The participants' results
- Method for the evaluation of the comparability of the results (assigned value and its associated measurement uncertainty, the establishment of the SDPA, range of results, graphical displays)
- Comparability of the participants' results and/or participants performance
- Comments and recommendations based on the outcome of the small ILC scheme

If some of the points are clearly included in the plan and the latter is provided to all the participants, then these issues do not need to be included again in the report.