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# **A015**

## **Proficiency Testing by Inter-laboratory Comparisons**

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## 1. Introduction

The purpose of accreditation is to attest to the proficiency of laboratories and other organizations to carry out specific activities involving conformity assessment.

Inter-laboratory comparisons are one of the reliable and effective ways of attesting to this proficiency as they make it possible to:

- determine the performance of laboratories concerning testing or specific measurements and to survey the continuing performance of the laboratories,
- identify the problems linked, for example, to the performance of the personnel or to the calibration of instruments and to indicate corrective actions,
- establish the efficiency and the comparability of new testing or measurement methods and to survey the established methods,
- increase the confidence of the clients in the laboratories,
- identify the differences between the laboratories,
- proceed to the validation of methods by at least the study of the reliability and exactness criteria,
- assign a level value of an analyte in a material to produce a reference material or, in the case that an inter-laboratory comparison is supervised by a certification authority, certify a level value in a material to produce a certified reference material,

The results of these inter-laboratory comparisons are also a way for OLAS to ensure consistency of calibration and test results between laboratories both on a national and international level.

These results of inter-laboratory comparison may as well be designed to meet the following objectives:



- evaluate the ability of the organizations concerned,
- evaluate the characteristics of a reference material,
- evaluate the characteristics of a non standardized method.
- assure the traceability of measurement results when the connection to the national and international measurement standards of the analysis, testing or calibration instruments are more difficult to realize for technical reasons or due to unrealistic costs (cf. Annex A016).

## 2. Definitions

- proficiency testing (of a laboratory): evaluation of a laboratory's performance in the area of calibration / tests, by means of inter-laboratory comparisons,
- inter-laboratory comparisons: organization, implementation and evaluation of calibrations / of tests on calibrated materials / the identical or similar test by at least two different laboratories under predefined conditions,

## 3. References

- ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing
- ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
- ILAC P9 Policy for Participation in Proficiency Testing Activities
- ~~EA 3/04 Use of Proficiency Testing as a Tool for Accreditation in Testing~~
- EA 4/18 Guidance on the level and frequency of proficiency testing participation

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## 4. Policy

In compliance with standards ISO/IEC 17025, ISO/IEC 17043 and with the document ILAC P9, OLAS promotes a policy of inter-laboratory comparisons for the concerned laboratories.

In compliance with the requirements of the EA and the ILAC, accredited laboratories and inspection bodies (where relevant) are obliged to resort to inter-laboratory comparisons where this is possible. The results obtained from the proficiency testing must be used by the CAB to maintain their skill levels. If these results are not satisfactory, they must implement adapted corrective actions to ensure maintaining of skill levels.

Before granting accreditation or for the extension to a new general domain, the CAB must have ~~participated~~ evidence of satisfactory participation to at least on inter-laboratory comparison in one of the main technical areas for which the accreditation will be granted. The identification of the main technical areas can be done in cooperation with OLAS.

Before an initial assessment, OLAS encourages the calibration laboratories to participate, when it's possible, to inter-laboratory comparisons organized by National Metrology Institutes.

If no inter-laboratory comparison program exists in a specified area, the accredited CABs must find other means to show their competence such as, the use of reference material or correlation with results of other laboratories or repeat testing or calibrations with equivalent methods (see ~~§ 5.9~~ § 7.7 of ISO/IEC 17025 standard).

In the frame of validation of methods, the CAB can use several techniques to determine their performances, in compliance with the requirements of the standard ISO/IEC 17025 (cf. ~~§ 5.4.5.2~~ § 7.2.2.1 note 2).

In the case of change of key staff of the CAB or in the case of an important modification of the technical appendix, OLAS can reduce the interval of participation planned by the laboratory for the inter-laboratory comparisons.



The performance of the CABs as well as the corrective actions is systematically controlled during the accreditation assessments.

## 5 .Procedure

Before each assessment, including initial assessments, the concerned laboratory or inspection body (where relevant) sends to OLAS the form *F023 – inter laboratories comparison program* which summarizes inter laboratory comparisons carried out or scheduled along with the frequency of participation. ~~The level of participation in interlaboratory assessments during an accreditation cycle is analysed in the form F032 – Review of participation in interlaboratory testing.~~

During the audits, OLAS proceeds to examine the results obtained from inter-laboratory comparisons and if necessary, also checks that identified corrective actions have been implemented.

The quality of the inter-laboratory comparisons programs will be controlled during the assessments.

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## 6. Choice of the programs of inter-laboratory comparisons

In order to guarantee a good quality of the inter-laboratory comparisons the laboratory should:

- choose a program of inter-laboratory comparisons in cooperation with OLAS,
- choose accredited organizers of inter-laboratory comparisons to deliver proficiency testing,
- choose a proficiency testing program in conformity with the essential recommendations of Guide ISO/IEC 17043 or ILAC P9,
- participate to inter-laboratory organized by EA in the frame of mutual recognition agreements in the concerned areas,
- refer to the data base EPTIS (<http://www.eptis.bam.de/>) that collects hundreds of inter-laboratory comparisons in the area of testing, calibration and medical biology.

OLAS recognizes the programs of inter-laboratory comparisons organized for the medical laboratories by the Direction de la Santé – Bureau de Contrôle de la Qualité. These inter-laboratory comparisons are organized based on the articles 12 and 13 of the law of the 16<sup>th</sup> of July 1984 concerning medical laboratories.