Title	**Proficiency Testing**
Reference	**RT-24**
Revision	**02**
Date	**2015-10-27**

NOTE: The present document represent the English version of document under reference at the specified revision. In case of conflict the Italian version will prevail. To identify the revised parts reference must be made to version in Italian language only.

Preparation	Approval	Authorisation	Application date
Director of the Dept. of Testing Labs	Directive Council	The President	2016-01-01

CONTENTS

1. INTRODUCTION

With reference to standard UNI CEI EN ISO/IEC 17011, par. 7.15, the accreditation body shall take into account, in the audit and in the decision-making process, the participation of the Testing Laboratories in Proficiency Testing and of other comparisons and of their results.

To maintain the multilateral EA agreements of multilateral mutual recognition, ACCREDIA shall demonstrate that it assesses the technical competence of the accredited laboratories, also through satisfactory participation at the Proficiency Tests and ILCs, both national and international.

2. SCOPE AND FIELD OF APPLICATION

The present Regulation identifies the various types of proficiency tests (PTs) and Interlaboratory Comparisons (ILCs), and how the results are managed and used by ACCREDIA-DL for the assessment of the technical competence of accredited and applicant Testing and Medical Laboratories (referred to in this document as “laboratories”)

3. REFERENCE STANDARDS

EA 4/18: “Guidance on the level and frequency of proficiency testing participation”

ILAC P9: “ILAC Policy for Participation in Proficiency Testing Activities”

UNI CEI EN ISO/IEC 17043: “Conformity assessment – general requirements for proficiency testing”

ISO 13528: “Statistical methods for use in proficiency testing by interlaboratory comparisons”

UNI EN ISO 15189: “Medical laboratories – requirements for quality and competence”

UNI CEI EN ISO/IEC 17025: “General requirements for the competence of testing and calibration laboratories”

UNI CEI EN ISO/IEC 17011: “Conformity assessment – general requirements for accreditation bodies providing accreditation of CABs”.

4. TERMS AND DEFINITIONS

Interlaboratory or Proficiency testing (PTs): evaluation of the performance of a participant in accordance with pre-established criteria using ILCs (UNI CEI EN ISO/IEC 17043 par. 3.7).
Interaboratory comparison (ILCs): providing, performance and evaluation of measurements or tests on the same or similar materials by two or more laboratories, in conformity with pre-established conditions (UNI CEI EN ISO/IEC 17043 par. 3.4).

5. DIFFERENT TYPES OF PROFICIENCY TESTS OR INTERLABORATORY COMPARISONS

PTs or ILCs can be sub-divided into the following main categories:

1. PTs proposed by competent and independent organisers:
   the participating Laboratory has the responsibility of auditing the competence of the organization, which shall provide evidence of accreditation against UNI CEI EN ISO/IEC 17043 or, at any rate, of operating in conformity with it.

Information is available on ACCREDIA's website – www.accredia.it – and also at www.eptis.barn.de, whose database provides information on the providers of PTs.

2. PTs organized by EA, by APLAC or offered as a part of international cooperation:
   in order to participate, ACCREDIA-DL selects one or more laboratories, depending on the accredited tests. The participating laboratories shall send the results to ACCREDIA or directly to the organization according to the specific instructions given at the moment of registration.

3. Measurement audits:
   measurement audits can be carried out by technical auditors during the course of the audits, when certified reference materials are available in order to verify the technical competence of each laboratory.

4. PTs based on bilateral comparisons:
   these can be acceptable when no other type of ILC is available. In these cases, as a statistical treatment of data is not possible, given the fact that data are insufficient and not representative, results are considered to have little meaning.

ILCs are widely used for many scopes and their use is growing internationally. Common scopes of ILCs include as follows:

a) evaluation of the performance of laboratories performing specific tests or measurements and monitoring of the performance of laboratories on a continuous basis;

b) identification of problems at laboratories and implementation of improvement actions where the problems might be related, for example, to testing procedures or inadequate measurements or to the effectiveness of staff training or supervision, or to the calibration of equipment.

c) definition of the effectiveness and comparability of testing or measurement methods;

d) assurance of additional trust in the laboratory's clients;

e) identification of interlaboratory differences;

f) training of participating laboratories on the basis of the results of such comparisons;

g) validation of declarations of uncertainty.

Interlaboratory evaluation tests do not generally include the points given below because the competence of laboratories in these applications is an a priori requirement. Such applications can also be used to give independent demonstrations of the competence of laboratories.

h) evaluation of the performance characteristics of a method;

i) assignment of values to reference materials and verifications of their suitability in specific testing and measurement procedures;

j) support for declarations of the equivalence for NIMs by means of key comparisons and supplementary comparisons conducted on behalf of the BIPM and of associated regional metrology bodies.

6. PARTICIPATION AT PROFICIENCY TESTS OR INTERLABORATORY COMPARISONS

In order to demonstrate technical competence and compliance with the requirements of point 5.9 of UNI CEI EN ISO/IEC 17025 and of point 5.6.3 of UNI EN ISO 15189 for medical laboratories, the laboratories shall participate in a sufficient number of interlaboratory comparisons, the results of which must be taken into account by the accreditation body, in both initial assessment and for maintenance of accreditation.

The laboratories shall communicate to ACCREDIA, using the relevant modules of the accreditation body, upon application for accreditation and in the subsequent documents related to the update or variation of the testing list or testing extension request, the results of participation at ILCs specifying the matrix, the testing method, the parameter, the disciplines and sub-disciplines (see the paragraph below), the year of participation and the identification data of the ILC.

Frequency of participation at ILCs – as for other activities related to assurance of quality of results, apart from those which are mandatory requirements – shall be established by the laboratory based upon risks connected with non-valid results for real samples and related to statistically evaluated results of ILCs which are not in conformity (ISO 13528).

Participation at ILCs, where applicable, shall include all accredited tests, in terms of materials/matrices/products, measurand/property measured and testing method.

Participation shall not be limited only to the more common tests and it shall always guarantee the inclusion of all the laboratory's testing techniques, both quantitative and qualitative.

The minimum requirements requested by ACCRDIA for participation are as follows:

- At least one analytical activity performed for each discipline before assessment for accreditation;
- At least one analytical activity performed related to each of the more important sub-disciplines after accreditation and before assessment for renewal of accreditation.

If there are no PTs available for the sector of competence, the laboratory shall provide evidence of the research work carried out and of the quality assurance activities (such as internal quality control, see also UNI CEI EN ISO/IEC 17025 par. 5.9 and UNI EN ISO 15189 par. 5.6.4).

The criteria of acceptability of the results are generally those proposed by the providing body although the laboratory can define other ones as long as they conform with UNI CEI EN ISO/IEC 17043, giving reasons for its chosen proposals.

The laboratories shall keep available for the ACCREDIA assessment team a summary of the results regarding participation at ILCs (date of performance, type of test, method used and evaluation of the providing body) and any actions brought in following non-conform results.

It is also advisable that the laboratories and inspectors, during the audit, take account not only of the Z-score (or other criterion used), but also of the other evaluations which may emerge from the statistical processing of data deriving from the ILC.

6.1 Outcomes of participation at PTs or ILCs

In the case of results which are not in accordance with the criteria of acceptability set down by the person in charge of the interlaboratory comparison, or by the laboratory itself, the laboratory shall provide evidence of having reviewed the entire analytical process to identify the causes of the nonconformity, and that the appropriate corrective actions have been implemented.

Following verification of the effectiveness of the corrective actions, the laboratory shall make an immediate request to the body providing the ILC, if this has not already been taken care of in the plan, to carry out a fresh research regarding the nonconformity in the subsequent sending of samples. If it is technically possible, it is advisable that the laboratory repeats the test on the same sample (re-sending of a sample identical to the one already examined and object of the nonconformity). If it is not possible for organisational and technical reasons, it will be possible to repeat the test (with the same measurand and method) also if another sample is used.

The laboratory shall communicate to ACCREDIA the test with a negative result which has not been resolved at the second recurrence, requesting suspension of use of the mark for that specific test. In case of failure of communication by ACCREDIA or during the assessment or following a specific request made by ACCREDIA to the providing body, ACCREDIA reserves the right to suspend accreditation of the laboratory.

7. IDENTIFICATION OF THE SECTORS AND OF THE TESTING TECHNIQUES

In order to satisfy the requirements of the present regulation, the laboratory shall, first and foremost, classify each of its accredited tests according to the materials/matrices/products, and disciplines and sub-disciplines. This classification leads to selecting the ILC involving all the tests which are part of a sub-discipline.

To define the disciplines and sub-disciplines it is necessary to identify the products/matrices/materials, measurands/ properties measured and the testing or measurement technique.

For example, if the products are taken into consideration, it is possible to include different products in the same sub-discipline as long as the matrices are of an equivalent nature (discipline: food; sub-discipline: milk, meat, cheese....).

If the property to be measured is taken into consideration, more than one property can be included (discipline: pollutants, sub-discipline: pesticide residues in food, IPA, dioxins etc.)

When principles of measurement are taken into consideration, however, it is not possible to include different measurement principles in the same sub-discipline (for example: Hg determined with ICP-MS cannot cover the use of the AA technique with cold vapours).

Each laboratory can have its own classification in disciplines or sub-disciplines which it shall document and justify.