



# Inter-laboratory Comparisons and Their Roles in Accreditation

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## Abstract

Results of interlaboratory comparisons and proficiency tests are a significant parameter for the calibration and testing laboratories for assuring the quality of test and calibration results performed by those laboratories. If test and calibration laboratories want to demonstrate that they operate according to a management system, that they are technically competent and that they can produce technically valid results in the tests and calibrations they perform for their customers, the general requirements they must meet are defined in ISO/IEC 17025:2017. This international standard forms the basis of international laboratory accreditation. Clause 7.7 Ensuring the validity of results in this standard requires laboratories to establish the procedures and instructions and other technical documentation needed to ensure the results of the tests and calibrations they perform. Participation in inter-laboratory comparison or proficiency testing programs is one of the most important of these activities. Participation in inter-laboratory comparisons provides an opportunity for laboratories to independently evaluate their analytical performance, both in absolute terms and in comparison, to other techniques.

In this study, information about calibration laboratories and accreditation activities is given and the importance of inter-laboratory comparison studies is explained to ensure the results of the measurements made by calibration laboratories.

**Keywords:** Accreditation, comparison, calibration, ISO17025, degree of equivalence, inter-laboratory comparison.

## Laboratuvarlararası Karşılaştırmalar ve Akreditasyondaki Rollerini

### Öz

Laboratuvarlar arası karşılaştırmaların ve yeterlilik testlerinin sonuçları, test ve kalibrasyon laboratuvarları tarafından gerçekleştirilen ölçüm sonuçlarının kalitesinin güvencesi açısından önemli bir parametredir. Laboratuvarlar, bir yönetim sistemine göre çalıştıklarını, teknik olarak yetkin olduklarını ve müşterileri için gerçekleştirdikleri test ve kalibrasyonlarda teknik olarak geçerli sonuçlar üretebileceklerini göstermek istiyorlarsa, yerine getirmeleri gereken genel gereksinimler ISO/IEC 17025:2017'de tanımlanmıştır. Bu uluslararası standart, laboratuvar akreditasyonunun temelini oluşturur. Bu standart içindeki madde 7.7, laboratuvarların gerçekleştirdikleri test ve kalibrasyonların sonuçlarının kalitesinin güvence altına alınmasını sağlamak için gerekli prosedürleri ve diğer teknik belgeleri oluşturmasını gerektirir. Laboratuvarlar arası karşılaştırma veya yeterlilik testi programlarına katılım bu faaliyetlerin en önemlilerinden biri olup bu sayede laboratuvarların performanslarını bağımsız olarak değerlendirmelerini sağlar.

Bu çalışmada kalibrasyon laboratuvarları ve akreditasyon faaliyetleri hakkında bilgi verilmekte ve kalibrasyon laboratuvarları tarafından yapılan ölçümlerin sonuçlarının sağlanması için laboratuvarlar arası karşılaştırma çalışmalarının önemi anlatılmaktadır.

**Anahtar Kelimeler:** Akreditasyon, Karşılaştırma, Kalibrasyon, ISO 17025, Denklik derecesi, laboratuvarlararası karşılaştırma.

## 1. Introduction

Accreditation is the independent, third-party evaluation of a conformity assessment body (such as certification body, inspection body or laboratory) against recognised standards, conveying formal demonstration of its impartiality and competence to carry out specific conformity assessment tasks (such as certification, inspection and testing) (ISO/IEC 17020:2012, 2012).

The general requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate to a management system, are technically competent and can generate technically valid results are contained within ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (BS EN ISO/IEC 17025:2017, 2018) standard. This international standard forms the basis for international laboratory accreditation. Section 7.7 of ISO/IEC 17025:2017 requires that laboratories shall plan and undertake quality assurance procedures for monitoring the validity of tests and calibrations undertaken. This shall include participation in inter-laboratory comparison or proficiency testing schemes where available and appropriate (UKAS Policy, 2019).

The laboratories who want to be accredited by accreditation bodies and want to continue the accreditation status that has been granted, such laboratories should carry out the necessary studies to demonstrate their technical competence and monitor this competence he is responsible for doing it. One way to demonstrate technical competence is the participation of laboratories in the appropriate PT and ILC organizations and achieve successful results. (TURKAK procure, 2020).

PTs are widely used for some purposes and their use is increasing internationally. BS EN ISO/IEC 17043:2010 "Conformity assessment - General requirements for proficiency testing" (BS EN ISO/IEC 17043:2010, 2010) international standard specifies general requirements for the competence of providers of proficiency testing schemes and the development and operation of proficiency testing schemes.

Inter-laboratory comparison (ILC) organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories under predetermined conditions. Proficiency testing (PT) evaluation of participant performance against pre-established criteria through inter-laboratory (ILC) comparisons. Participant laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency provider (BS EN ISO/IEC 17043:2010, 2010).

Typical purposes for ILC include the following items

- a) evaluation of the performance of laboratories for specific tests or measurements and monitoring laboratories' continuing performance;
- b) identification of problems in laboratories and initiation of actions for improvement which, for example, may be related to inadequate test or measurement procedures, the effectiveness of staff training and supervision, or calibration of equipment;
- c) establishment of the effectiveness and comparability of test or measurement methods;
- d) provision of additional confidence to laboratory customers;

- e) identification of interlaboratory differences;
- f) education of participating laboratories based on the outcomes of such comparisons;
- g) validation of uncertainty claims;
- h) evaluation of the performance characteristics of a method – often described as collaborative trials;
- i) assignment of values to reference materials and assessment of their suitability for use in specific test or measurement procedures
- j) support for statements of the equivalence of measurements of National Metrology Institutes through "key comparisons" and supplementary comparisons conducted on behalf of the International Bureau of Weights and Measurement (BIPM) and associated regional metrology organizations.

Proficiency testing involves the use of ILC comparisons for the determination of laboratory performance, as listed in a) to g) above. PT does not usually address h), i) and j) because laboratory competence is assumed in these applications, but these applications can be used to provide independent demonstrations of laboratory competence.

## 2. Material and Method

### 2.1. Technical Requirements for PT Providers

In general, the development and operation of proficiency testing schemes shall be undertaken by proficiency testing providers having the competence to conduct inter-laboratory comparisons and access to expertise with the particular type of proficiency test items.

On the personnel side, the proficiency testing provider shall have managerial and technical personnel with the necessary authority, resources and technical competence required to perform their duties. The proficiency testing provider's management shall define the minimum levels of qualification and experience necessary for the key positions within its organization and ensure those qualifications are met.

The proficiency testing provider shall ensure that there is an appropriate accommodation for the operation of the proficiency testing scheme. This includes facilities and equipment for proficiency test item manufacturing, handling, calibration, testing, storage and despatch, data processing, communications, and retrieval of materials and records.

### 2.2. Design of PT Schemes Planning

The proficiency testing provider shall identify and plan those processes which directly affect the quality of the proficiency testing scheme and shall ensure that they are carried out under prescribed procedures. The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme. The name and address of the proficiency testing provider, criteria to be met for participation, the number and type of expected participants in the proficiency testing scheme, selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round, a description of the range of values or characteristics, or both, to be expected for the proficiency test items, storage and

distribution of proficiency test items, a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements, preparation of any standardized reporting formats to be used by participants, a detailed description of the statistical analysis to be used, the origin, metrological traceability and measurement uncertainty of any assigned values, criteria for the evaluation of performance of participants, a description of the data, interim reports or information to be returned to participants, a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public and actions to be taken in the case of lost or damaged proficiency test items (BS EN ISO/IEC 17043:2010 , 2010).

### **2.3. Operation of PT Schemes and Instructions for Participants**

The proficiency testing provider shall give participants sufficient prior notice before sending proficiency test items, providing the date on which the proficiency test items are likely to arrive or to be despatched unless the design of the proficiency testing scheme makes it inappropriate to do so. The proficiency testing provider shall give detailed documented instructions to all participants about the plan and the progress of the proficiency testing.

### **2.4. Data Analysis and Evaluation of PT Results**

All data processing equipment and software shall be validated under procedures before being brought into use. Computer system maintenance shall include a backup process and system recovery plan. The results of such maintenance and operational checks shall be recorded. Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting. The proficiency testing provider shall use valid methods of evaluation that meet the purpose of the proficiency testing scheme. The methods shall be documented and include a description of the basis for the evaluation. The evaluation of performance shall not be subcontracted.

### **2.5. Reports**

Proficiency test reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants. The authorization of the final report shall not be subcontracted. Where all original data cannot be reported to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied. Reports shall include the name and contact details for the proficiency testing provider the name and contact details for the coordinator, the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report, the date of issue and status (e.g. preliminary, interim, or final) of the report, page numbers and a clear indication of the end of the report, a statement of the extent to which results are confidential, a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment, the participants' results, statistical data and summaries, including assigned values and range of acceptable results and graphical displays, details of the

metrological traceability and measurement uncertainty of any assigned value, procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation, assigned values and summary statistics for test methods/procedures used by each group of participants, procedures used to statistically analyse the data. All information supplied by a participant to the proficiency testing provider shall be treated as confidential.

### **2.6. Policies on participation in PT schemes**

If relevant, interested parties should document their policies for participation in PT schemes. The frequency of participation, the criteria used by an interested party to judge satisfactory or unsatisfactory performance, whether participants may be required to participate in follow-up PT schemes if performance is judged to be unsatisfactory, how the results of PT will be used in the evaluation of performance and the subsequent decision should be defined by participants.

All methods and matrices within the scope of accreditation should be determined by the laboratories, and sub-areas should be determined and participation in comparison measurements in different parameters should be ensured in the sub-areas by participant laboratories. For such purpose, the "EA-4/18: Guidance on the Level and Frequency of Proficiency Testing Participation" document can be referred to (EA-4/18 standard, 2010).

## **3. Results and Discussion**

Technical competence can also be demonstrated by participating in interlaboratory comparison programs that are not organized as proficiency tests and achieving successful results. Proficiency tests and inter-laboratory comparison programs are important tools for accreditation bodies to see the proficiency of the laboratory that wants to be accredited and to evaluate the quality of its activities. Laboratories applying for accreditation are required to carry out activities according to the following criteria regarding proficiency tests or interlaboratory comparisons.

In the accreditation decision process, the proficiency tests of the laboratories and the inter-laboratory comparison participation plans, their participation, and the results they obtained are examined and evaluated. If there are unsuccessful results of the laboratory, the corrective actions taken by the laboratory are examined and evaluated. Options such as applying different surveillance intervals can be implemented if the laboratory consistently achieves successful results.

The results from proficiency testing schemes are useful for both participants and accreditation bodies. There are, however, limitations on the use of such results to determine competence. Successful performance in a specific proficiency testing scheme may represent evidence of competence for that exercise, but may not reflect ongoing competence. Similarly, unsuccessful performance in a specific proficiency testing scheme may reflect a random departure from a participant's normal state of competence. It is for these reasons that proficiency testing should not be the only tool used by accreditation bodies in their accreditation processes. For participants reporting unsatisfactory results, the accreditation bodies should have policies to ensure that the participants investigate and comment on their performance within an agreed time-frame, and take appropriate corrective action, (where necessary) ensure that the participants undertake any subsequent proficiency testing to confirm that any

corrective actions taken by them are effective, and (where necessary) ensure that on-site evaluation of the participants is carried out by appropriate technical assessors to confirm that corrective actions are effective.

One of the commonly employed analyse methods in PT measurement is determining the degree of equivalence by calculating normalise error (En) values for each participant laboratory for each calibration point. In the analysing of the degree of equivalence, participants' results are compared to "reference values" that are obtained from the National Metrology Institutes or other credible sources. The comparison takes into account the difference between laboratories' results and the reference values, as well as the uncertainties associated with both. The normalised error ratio (En ratio) analysis is calculated based on equation (1).

$$E_n = \frac{|L_V - R_V|}{\sqrt{U_{L_V}^2 + U_{R_V}^2}} \quad (1) \text{ (BS EN ISO/IEC 17043:2010, 2010)}$$

where,

LV is the value reported by the laboratory, with expanded uncertainty ULV.

RV is the reference value, with expanded uncertainty URV.

The  $E_n$  the ratio should usually be within the range  $\pm 1$ . If the analysis reveals that it lies outside this range, results are labelled as unsuccessful. So, it is expected to investigate the results and require that any necessary corrective and preventive actions are undertaken. The assessment team will assess the activities of the laboratory in resolving any issues.

Participant values vs reference value (weighted mean) taken from the international PT organization report were given in Figure 1.

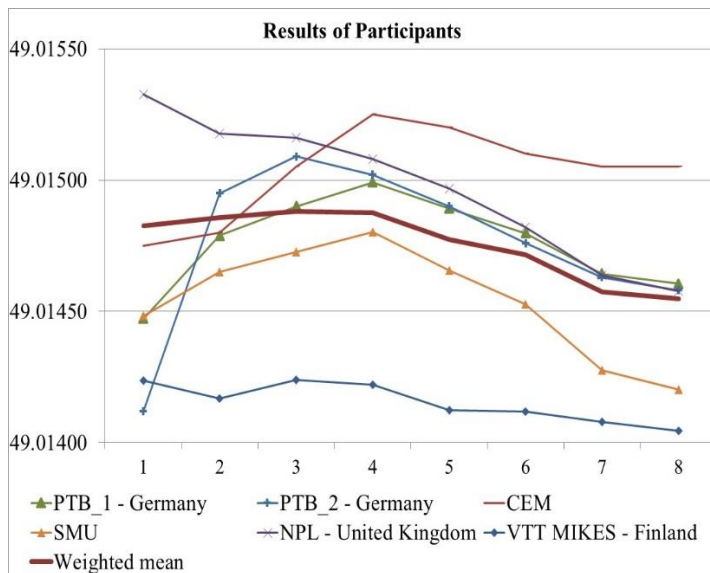


Figure 1. Participant values vs reference value (weighted mean) of PT (Altintas, 2020)

Using the results of participants and reference value and assigned uncertainties available in EURAMET.M.P-K1.c (Altintas, 2020) report, En values can be calculated based on the equation (1). En values of participants were given in Figure 2.

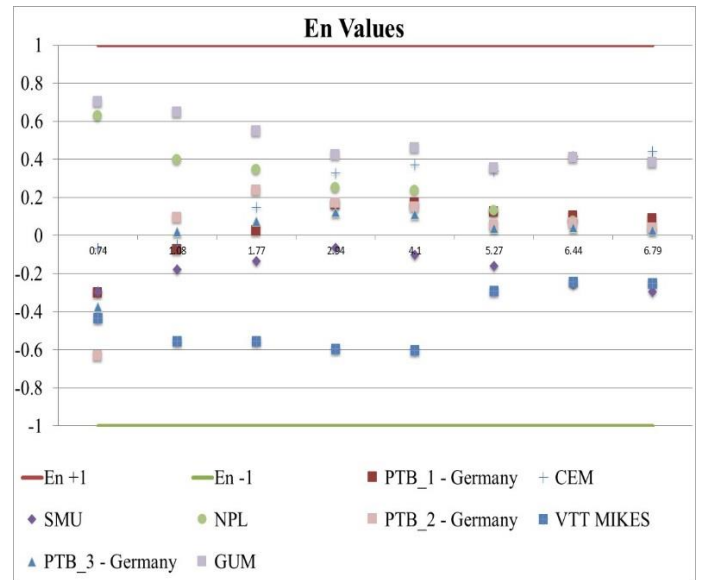


Figure 2. En values of participants (Altintas, 2020)

Based on the En criteria it can be concluded that all participant laboratories show the degree of equivalence to the assigned reference value

#### 4. Conclusions and Recommendations

Participants may need to demonstrate their competence to other interested parties, such as customers or in a subcontracting mandate. Proficiency testing results, as well as other quality control activities, can be used to demonstrate competence, although this should not be the only activity. Proficiency testing data used to validate claims of competence are normally used by organizations in conjunction with other evidence, such as accreditation. It is the responsibility of the participants to ensure that they have provided all the appropriate information to interested parties wishing to evaluate the participants as to their competence. The results from proficiency testing schemes are useful for regulatory bodies that need to evaluate the performance of participants covered by regulations. It is the most important parameter that is asked by the accreditation bodies at the accreditation application and by the assessors during the assessment visit. Successful PT results are necessary for terms of ensuring the quality of produced results by laboratories according to clause 7.7 in the ISO/IEC 17025:2017. The TS EN ISO/IEC 17043 standard determines the general conditions regarding the competence of its providers, the organization of PT measurement, and the execution of this organization (Alper, 2013). It has been observed that the comparison measurements carried out by the providers by adhering to the TS EN ISO / IEC 17025 standard until today is more effectively carried out and concluded when compared with the comparison measurements organized according to the TS EN ISO / IEC 17043 standard. In our country, there is no provider accredited under 17043 yet. As of September 2021, the number of accredited calibration laboratories in our country is 147, the number of test laboratories is 938 (Akredite kuruluş Arama, 2021] and the numbers are increasing rapidly. In this study, the role of PT tests in assuring the quality of measurements made in laboratories, the organization of PT tests, the analysis and reporting of their results, and the role of these PT tests during accreditation and accreditation inspections are mentioned



## References

- ISO/IEC 17020:2012 Conformity assessment-requirements for operation of various types of bodies performing inspection, ISO std. (2012).
- BS EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, ISBN 978 0 539 01414 3, The British Std.Inst., 2018.
- UKAS policy for participation in measurement audits and interlaboratory comparisons, UKAS, Edition 4, May 2019.
- P704 Yeterlilik deneyleri ve laboratuvarlar arası karşılaştırma programları prosedürü, Türk Akreditasyon Kurumu, Revizyon 11, 15.05.2020.
- BS EN ISO/IEC 17043:2010 Conformity assessment - General requirements for proficiency testing, ISBN 978 0 580 56522 9, Standards Policy and Strategy Committee, May 2010.
- EA-4/18: Guidance on the Level and Frequency of Proficiency Testing Participation, European accreditation, June 2010.
- A. Altintas, I. Kocas, Y. Durgut, J. Bartolo, M. Bergoglio, L. G. Bermanec, A. Bošnjaković, S. Burzić, A. Condereys, M. Dobre, P. Farar, P. Hetherington, N. Medina, W. Sabuga, O. Ott, T. Konczak, I. Sandu, J. Setina., D. Steindl, C. Vámosy, B. Waller, C. Wuethrich, A. Brzozowski, J. V. Geel, S. Saxholm, F. Arrhén, “Final report on key comparison EURAMET.M.P-K1.c in the range 0.7 MPa to 7.0 MPa of gas gauge pressure”, Metrologia, vol. 57, Number 1A, 2020.
- Alper, M. P., Ince, A. T. (2013, September). TS EN ISO/IEC 17043 Yeterlilik Testleri İçin Genel Şartlar standardına uygun olarak karşılaştırma ölçümlerinin organizasyonu, Paper presented at the 8<sup>th</sup> National Measurement&Science Congress
- Akredite kuruluşlar. (2021, 25 Eylül). Erişim adresi <https://www.turkak.org.tr>