

Use of proficiency testing in accreditation

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Scope:

This rule conduces to the implementation of international requirements and the summarization of the national requirements for the use of proficiency testing in the accreditation process of testing and calibration laboratories, medical laboratories (in the following described as laboratories) and also inspection bodies¹. It describes the requirements for participation in proficiency test at accreditation of abovementioned conformity assessment bodies (CAB) and contributes to a harmonized implementation by the auditors across all the different departments. Further concreted rules for the involvement of proficiency tests into the accreditation which are created by the sector committee of the Deutschen Akkreditierungsstelle GmbH (DAkkS) apply additionally.

Date of the confirmation by the accreditation advisory board: 12.04.2016

Substantive changes in comparison to the previous issue of this rule are marked with a line on the right side or highlighted with a **yellow** background.

¹ The presented requirements apply for inspection bodies for testing as well as for the actual inspection activities. It is accepted that proficiency tests for inspection activities are not able to be processed because of insufficient availability in many fields.

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1 Purpose / Scope

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2 Terms / Definitions

Proficiency Testing, PT	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (DIN EN ISO/IEC 17043:2010)
Ring Trial	Organization, performance and evaluation of measurements/tests on the same or similar test objects by two or more laboratories in accordance with predetermined conditions
Interlaboratory Comparison, ILC	Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (DIN EN ISO/IEC 17043:2010)
Measurement Technique	The process of testing/calibrating/identifying the property, including any pretreatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement) (EA 4/18:2010)
Property	The quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, Force) (EA 4/18:2010)
Product	The item that the measurement technique is being applied. (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete) (EA 4/18:2010)

Level of Participation	The number of sub-disciplines that an organization identifies within its scope, and therefore the number of specific proficiency tests that should be considered for participation (EA-4/18:2010)
Frequency of Participation	Interval for participation in a proficiency test sub-discipline. Intervals may vary from sub-discipline to sub-discipline within a laboratory.
Sub-discipline	An area of technical competence defined by a minimum of one measurement technique, property and product, which are related. (e.g. Determination of Arsenic in soil by ICP-MS) (EA-4/18:2010)
Availability of proficiency tests	Proficiency tests are available, if they are offered by proficiency test providers and the required documents are provided in the national language of the participating body or in English.
Technical adequacy of proficiency tests	A proficiency test is regarded as technically adequate, if its scope similar to the daily practice in the participating body. In case of specific measurement techniques, for which no exact consistent proficiency test is available, it may be adequate to choose a proficiency test, which is similar to the scope or which covers an important partial aspect of the task.
Economical adequacy of proficiency tests	Proficiency test are regarded as economical adequate, if the entire costs of proficiency test have no considerable influence on the price of the test or calibration . In this instance the costs of the proficiency tests plus the costs which would be charged to a third party for this test of such a sample on the market, should be calculated. If for a test normally no prices are obtained (e.g. public CAB) so the internal efforts (staff and material costs) need to be considered.

3 Description

3.1 Introduction/Principles

The standard DIN EN ISO/IEC 17025:2005 requires in chapter 5.9 that laboratories have to plan, introduce and apply quality control procedures to ensure the results of their tests **or calibrations** performed. Among other things the participating in proficiency tests is supposed. The DIN EN ISO/IEC 17011 expects from international recognized accreditation bodies that they demand the participation in proficiency test programs and other comparison programs of the laboratories accredited by them. This general requirement is specified by the International Laboratory Accreditation Cooperation (ILAC) and European Cooperation for Accreditation (EA) in the documents ILAC-P9:2014 and EA-4/18:2010.

This rule summarizes the international requirements and interprets them, if necessary, to ensure a basis for the harmonized procedure of the assessment of laboratories and inspection bodies as part of the accreditation of DAkKS.

3.2 Requirements for the CAB for participation in proficiency tests/interlaboratory comparisons

Proficiency tests are an essential instrument of the quality assurance in laboratories and if applicable in inspection bodies. It provides an opportunity to review the competence for implementation of test and calibration methods or inspections and the viability of the management system independently. Within the scope of their assessments the Deutsche Akkreditierungsstelle GmbH (DAkKS) includes also the results of proficiency tests to review and assess the compliance with requirements of DIN EN ISO/IEC 17025 or DIN EN ISO/IEC 17020 in laboratories and inspection bodies.

For the attainment and maintaining of their accreditation laboratories and inspection bodies are committed to prove the successful participation in proficiency tests and interlaboratory comparisons as long as these are available and also technically and economically adequate. In addition specific determinations of the sector committees need to be taken into account, if applicable. In the case that no proficiency tests in the abovementioned context are offered, the laboratories need to prove if they can participate in any interlaboratory comparisons between two or more laboratories or may organize them by themselves. Interlaboratory comparisons for the purpose of method validation or certification of reference materials on specific conditions may be also accepted as proficiency tests.

The DAkKS demands the successful participating in at least one proficiency test on the abovementioned conditions in every defined sub-discipline in the period between initial accreditation and reaccreditation or between two reaccreditations. Before the attainment of initial accreditation the successful participation in proficiency tests that are representative for the applied scope of accreditation need to be proved. On the basis of technical recommendations of its committees the DAkKS may define more frequent participation in proficiency tests, if applicable. Additionally the technical field-specific regulations need to be considered. Proficiency tests on the basis of regulatory requirements or other obligations of the CAB are also required for an accreditation.

The DAkKS endeavors to involve the laboratories and inspection bodies, which are accredited by them, as often as possible in international proficiency tests to support EA with its effort to proof the viability of the Multilateral Agreement for mutual recognition of EA. These by EA recommended international proficiency tests of APLAC (Asia Pacific Laboratory Accreditation Cooperation), IRMM (EU Joint Research Center Institute for Reference Materials and Measurements) and of professional suppliers, will be accepted alternatively to proficiency tests of national suppliers as long as the latter are not required for regulatory purposes.

Proficiency tests, which are the basis of governmental recognitions/approvals/notifications (e.g. drinking water ordinance, technical modules) or compulsory in another way (e.g. WADA proficiency tests), will basically be recognized within the context of this rule. In case that accreditation is required for recognitions, the compliance of these obligations for participating in proficiency tests may be monitored by DAkkS, if this is not regulated in another way by law or regulatory requirements.

If a CAB does not participate or participates only partially successfully in proficiency tests, which are available and adequate for the CAB, then it might have consequences for the accreditation of the CAB. In principle insufficient participation in a single proficiency test does not have immediate consequences for the accreditation. Incorrect or insufficient proficiency test results need to be processed as nonconforming testing (inspection). In case that the **frequency of participation** in proficiency tests is not sufficient or is continuously unsuccessful, further proficiency tests or additional assessments may be imposed. Also a restriction of the accreditation may not be excluded.

3.3 Implementation of the requirements by the CAB

The extent and the frequency of participation in proficiency tests for a specific sub-discipline needs to be determined by the CAB considering sectoral and other external requirements for participation in proficiency tests and taking into account the specifications of the sector committees. Therefore a general PT-strategy within the quality management system documentation needs to be described. Upon its determination also alternatives and further aspects should be considered, such as:

- requirements on the basis of laws and regulations in the context of regulatory recognitions/approvals etc.;
- internal measures for quality assurance as the use of (certified) reference materials; use control charts; application of different methods for the determination of the same parameter, also as alternative, if no respective interlaboratory testings are on offer; etc.;
- the risk potential of false results within the respective sub-discipline;
- the quantity of the performed tests/calibrations/inspections and also the significance and the effect on the final use of the results;
- the qualification of the personnel;
- the number of employees concerned with the method.

Furthermore the following described measures are required.

3.3.1 Proficiency test strategy of the CAB

Every CAB needs to frame a strategy which describes the dealing with proficiency tests with respect to its scope of accreditation. This strategy should consider the following aspects:

- general obligation to participate in proficiency tests;
- statement to the extent and frequency of the participation in proficiency tests with reference to a proficiency test plan;
- if applicable, the participation in mandatory proficiency tests on statutory or other compulsory basis having regard to determinations of the sector committees;
- if applicable, the opportunity to organize interlaboratory comparisons on its own, in the case proficiency tests are not available;
- analysis of every proficiency tests with the help of the affected staff;
- application of the process for the control of nonconforming testing work and implementation of corrective actions in the case of defective results within proficiency tests.

3.3.2 Proficiency test planning

The CAB needs to combine its test, calibration and inspection methods to so-called sub-disciplines and determine with respect to the demands in which suitable proficiency tests it will take part. The necessity and frequency of the participation in proficiency tests within the respective sub-discipline need to be scheduled by the CAB on a plan for at least 3 or better 5 years. An example for this regulation is to be found in attachment 2 of this rule². This plan shall be adapted continuously concerning the current requirements but at least once a year, e.g. during the management review.

Sub-disciplines need to be defined by the test, calibration or inspection methods, the parameters and the products/matrices. The principle shall be to define fields within which the results of proficiency tests are transferable. Examples with explanations are to be found in attachment 1 of this rule².

A sub-discipline may contain also several measurement techniques, parameters and products/matrices as long as the equivalence and comparability can be proved. A point of reference on determination of a sub-discipline is, that it normally should not require different technical competencies neither different skills/experiences of the personnel nor different measurement equipment.

The determination of a sub-discipline should be processed incrementally. Beginning with the measurement technique the parameters and finally the products shall be assigned to the sub-discipline. If applicable, several products/matrices or parameters may be linked to a test method within a specific sub-discipline or backwards:

² Available only in German language

- With respect to the measurement technique;
It is possible, but mostly not useful to include different measurement techniques in the same sub-discipline.
- With respect to the properties/analytes/parameters to be determined;
It may be possible to include more than one parameter in the same sub-discipline.
- With respect to the product/matrices to be tested;
It may be possible to include different products/matrices in the same sub-discipline provided that the including products/matrices, objects or materials are connatural or act similar while the measurement.

In the case a CAB includes several measurement techniques in one sub-discipline so it needs to justify that the results of a proficiency test are transferable to the different measurement techniques, e.g. on the basis of validation data. The assessors review this justification on acceptability.

The plan of frequency and extent of participation in proficiency tests needs to be summarized in a chart, which needs to be provided to the DAkkS and also to the assessors before a scheduled assessment. An example for such a chart is to be found in attachment 2².

The EPTIS (Worldwide PT Database) (<http://www.eptis.bam.de>) database is recommended for information concerning supplies of proficiency tests. It contains information about proficiency tests worldwide. But this is not the exclusively source for information about proficiency tests. For some testing fields there are proficiency tests from quality assurance associations, providers of quality labels, technical associations, which are not listed in the EPTIS system.

3.3.3 Evidence of participation in proficiency tests

To ensure an effective assessment of the participation in proficiency tests, the CAB has to create a summarizing chart of all proficiency tests it takes part in the period of at least two years ago plus the proficiency tests in the current year, no matter if an evaluation for the particular proficiency test already exists. The participation has to be evaluated with respect to each parameter. The chart has to contain at least following information, if available:

- Sub-discipline;
- dates of execution of the proficiency test;
- proficiency test provider;
- product/matrix;
- investigated parameters;

- non-successful/passed parameters – where possible including evaluation criteria, e.g. z-score or E_n -values;
- corrective actions (keywords) for non-successful/passed parameters.

Before every assessment the recent proficiency test list needs to be provided to the accreditation body and the assessors. The documents and raw data for the proficiency tests including the records of the implemented corrective measures in case of non successful parameters have to be available easily on-site and provided to the assessor in the assessment. An example for such a list is to be found in attachment 2².

4 Applicable documents

DIN EN ISO/IEC 17011 2005	Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies
DIN EN ISO/IEC 17020 2012	Conformity assessment — Requirements for the operation of various types of bodies performing inspection
DIN EN ISO/IEC 17025 2005	General requirements for the competence of testing and calibration laboratories
DIN EN ISO/IEC 17043 2010	Conformity assessment – General requirements for proficiency testing
EA 4/18:2010	Guidance on the level and frequency of proficiency testing participation
ILAC P9:06/2014	ILAC Policy for Participation in Proficiency Testing Activities