DAkkS
Deutsche
Akkreditierungsstelle

Rules for accreditation of providers of proficiency testing/inter-laboratory tests

71 SD 0 007 | Revision: 1.1 | 16. October 2013

Scope:

With this regulation the requirements for accreditations of providers of proficiency testing/inter-laboratory tests/ring tests/external quality assurance programmes (EQA), hereinafter called PT-provider, will be explained. In order to ensure an interdisciplinary harmonization of requirements and processing on the application of DIN EN ISO/IEC 17043, statements for interpretable requirements of the standard will be made. These general rules apply to PT-provider in the testing-, calibration- and inspection area with or without testing- or calibration laboratories.
Further requirements for provider of external quality assurance programmes in laboratory medicine which offer proficiency testing within the regulation 98/79/EC and DIN EN 14136 and for which they are or will be accredited are described within the sectoral “Rules for the accreditation of EQAS organizations regarding to regulation 98/79/EC are presented.
These regulations also include requirements to the accreditation- and assessment activities of DAkkS in the area of the accreditation of PT-provider.

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1 Scope and intention

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Further requirements for provider of external quality assurance programmes in laboratory medicine which offer proficiency testing within the regulation 98/79/EC[2] and DIN EN 14136[3] and for which they are or will be accredited are described within the sectoral "Rules[4] for the accreditation of EQAS organizations regarding to regulation 98/79/EC are presented.
These regulations also include requirements to the accreditation- and assessment activities of DAkkS in the area of the accreditation of PT-provider.

2 Terms

For the terms used in this documents the definitions of DIN EN ISO/IEC 17043, DIN EN 14136, regulation 98/79/EC, ISO/IEC Guide 99[5] and the DIN EN ISO/IEC 17000[6] apply.

3 General requirements for accreditation

3.1 General

PT-provider will be accredited on request regarding to the requirements of the standard DIN EN ISO/IEC 17043. In the process of the accreditation there will be at least one exemplary assessment of a performed proficiency testing for all applied areas. For proficiency testing that is completely comparable to others it might be possible to reduce the assessment extends.
PT-providers are obligated to meet the relevant General rules for accreditation of conformity assessment bodies (71 SD 0 001). Exclusively PT-provider will be accredited who perform proficiency testing of laboratories and Inspection bodies for evaluation of their performance.
Exclusively PT-provider will be accredited who can prove the technical competence, for the areas accreditation is applied for and proficiency testing will be offered.

1 DIN EN ISO/IEC 17043 : 2010: Conformity assessment - General requirements for proficiency testing
2 DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27. October 1998 on in vitro diagnostic medical devices, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18. Juni 2009
3 DIN EN 14136 : 2004: Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
4 71 SD 3 018: Rules for the accreditation of EQAS organizations regarding to regulation 98/79/EC
5 ISO/IEC Guide 99: International vocabulary of metrology - Basic and general concepts and associated terms (VIM)
6 DIN EN ISO/IEC 17000 : 2005: Conformity assessment - Vocabulary and general principles

Furthermore the following activities have to be performed by themselves and shall not be subcontracted (see DIN EN ISO/IEC 17043 section 5.5):

- The planning of the proficiency testing sheme
- The evaluation of performance
- The authorization of the final report and of the certificates of attendance, respectively.

PT-providers have to adopt relevant measures needed for the fulfilment of requirements which result of amendments of the legal position, of accreditation rules and recognised rules of technology.

3.2 Specifications on the requirements of the DIN EN ISO/IEC 17043:2010

The following numbering refers to selected sections of the DIN EN ISO/IEC 17043 to facilitate locating the respective part in the standard.

4 Personnel

4.2.2 Manager and deputy manager

The manager of the PT-provider and its representative must have qualifications as described below:

- *University degree in medical, scientific or engineering, in special cases equivalent skills,*
- *At least 3 years of professional work of which at least 2 years of the employment were with conformity assessment duties in technical areas which correspond to the scope of accreditation, e. g. in a calibration-, testing-, surveillance- or certification body as laid down in the DIN EN ISO/IEC 17000 series,*
- *Knowledge about quality management procedures especially as laid down in the DIN EN ISO/IEC 17000 and DIN EN ISO 9000 series and due to the successful participation to relevant training and /or practical experience,*
- *Specific knowledge in the relevant legal areas within the scope of accreditation, if applicable.*

4.2.3 *employed external staff has to be bound by contract (permanent or project related). Contracts have to include at least the following:*

a. *Description of the activities*
b. *The time needed for these activities*
c. *Rules on confidentiality, independence and freedom from conflicts of interest*
d. *Integration into the quality management system*
e. *Regulations on further trainings*
f. *Storage of personal data such as training documents*
g. *The term of the contract*

4.3 Equipment, accommodation and environment

4.3.4 *If applicable, the provider has to prove that the required conditions which are relevant for the quality of proficiency test- / calibration items and for the performed tests, calibrations or measurements are respected during the transport at any time.*

4.3.6 *The evidence of accreditation for testing methods which are used for homogeneity-, stability- and content determination is sufficient for the demand of validation of testing methods. This applies also if the methods are part of an accreditation for the relevant calibration scope. Thereby the accredited calibration scope including the smallest assignable measurement uncertainties are decisive. If an accreditation does not exist a validation of the in-house methods are necessary, for standard methods proof shall be provided that the performance characteristics described in the standard are met.*

4.4 Design of proficiency testing schemes

4.4.1.3 *During initial accreditations a written procedure is required which presents the processes for the planning of proficiency testing schemes. Furthermore for initial accreditation and for each scope accreditation is applied for it has to be proved that the requirements of the standard has been fulfilled in the planning of proficiency testing or that they are not relevant. As part of surveillance the planning of all accredited proficiency testing schemes will be reviewed regarding the standard requirements.*
In case of amendments of proficiency testing schemes the planning documents have to be revised correspondingly. The development including the planning of new proficiency tests have to be clearly traceable. The specifications which are named within the planning documents have to be matched with the actual results achieved.

4.4.1.4 *The PT-provider may appoint advisory groups or technical experts for utilizing additional expertise. The following documents have to be allocated:*

a. *List of experts appointed for several areas in which proficiency testing is performed*
b. *Information on the technical knowledge of the experts*

It has to be comprehensible for the assessor to which extent advisors are engaged.
For meetings with the experts recordings have to be made, e. g. protocols, notes on telephone conversation or e-mail communication for being able to track all relevant decisions which have been resolved regarding proficiency testing.
If advisory groups are appointed these must have fundamental regulation on their functioning. Deliberations of these groups must be recorded to provide traceability for decision processes. These fundamental regulations should contain the following minimum contents:

a. *Tasks (according to 4.4.1.5 of the DIN EN ISO/IEC 17043)*
b. *Selection of members, including selection criteria*
c. *List of members with contact details and technical background*

d. *Frequency and time needed for deliberations as well as their recording*
e. *Statements on confidentiality, on independence and on freedom of conflicts of interest*
f. *If applicable subgroups*
g. *Acceptance, amendment and coming into force of rules of procedure*

4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 *Commercially available equipment and software for data processing are considered to be validated, whereas e. g. based on test sets of data the functionality according to the intended purposes is to be verified. As well for self-programmed software for the data processing the functionality according to the intended purposes has to be proved on the basis of a sufficient number of test sets of data.*

4.9 Communication with participants

4.9.5 *If individual certificates of attendance are issued in addition to proficiency testing reports these have to be designed in a non misleading way. They should contain at least the following:*

a. *Subject and extent of the proficiency testing (including indication of the parameters investigated)*
b. *Name and address of the PT-provider*
c. *Designation of the participant and code number*
d. *Number of the proficiency test*
e. *Reference to the final report*
f. *Page number of the certificate of attendance*
g. *Name as well as function and signature of the authorized signatory*
h. *Date of execution of the proficiency testing scheme*
i. *Criteria for the evaluation, e. g. %80 of the delivered results with a z-score lower than 3 passed or all En-values with an amount lower than 1*
j. *Results of the participant*

If an appraisal is made, e. g. „successfully passed“, the grounds of the appraisal must be declared on the certificate of attendance / the certificate.
If an electronic procedure will be used for signing, the PT-provider has to establish regulations which ensure that requirements on function and safety are met to the same extend as a conventional signature. In particular this is valid for a one to one, comprehensible and counterfeit proof assignment of the electronic signature to the person authorized to sign. Statutory provisions have to be respected.

5. Management requirements

5.1 Organization

PT-providers must have regulations on possible liability claims which result of their activities (e. g. liability insurance, risk assessment, reserves).

5.4 Review of requests, tenders and contracts

There are two scenarios for consideration. On the one hand a proficiency testing provider can be assigned by a customer to organize proficiency testing for a group of laboratories, e. g. in respect of a tender or for supplier laboratories of a manufacturer. In this case the requirements of clause 5.4 shall be taken into account.

On the other hand when laboratories or inspection bodies participate on routine proficiency tests, the requirements of clause 5.4 must be fulfilled by the PT-provider in a respect that the customer has been sufficiently informed to estimate the benefit that can be drawn by participation in the proficiency test.

5.5 Subcontracting services

A PT-provider can subcontract parts of the organization of the proficiency testing. However the PT-provider must have the competence to evaluate the results of the subcontracts. It must clearly be evident which work has been subcontracted for each proficiency testing. Participants must be informed in advance, at least generally, about the subcontracting of parts of the proficiency testing. Such information could be:"Parts of the proficiency testing will be processed by a competent subcontractor".

The planning of proficiency testing, the evaluation of performance and the authorization of the final report or certificate of attendance must not be subcontracted. (cf. 3.1)

The production of the test material is only considered as a subcontract if tests to the content, homogeneity and to the stability or further applicable characteristics of the test material are included within the production process.

The fulfilment of relevant requirements of the applicable standard by subcontractors and their competence must be proved by the PT-provider. The scope of the competence evaluation of subcontractors by the PT-provider depends on the complexity of the provided tasks.

Requirements can be fulfilled through

- *e. g. an accreditation as testing- or calibration laboratory regarding to DIN EN ISO/IEC 17025 for the testing methods or the calibration extent in question (the smallest assignable measurement uncertainty must be suitable for the purpose of the proficiency testing) with testing-, calibration- and inspection procedures for the subcontractor is available or as an inspection body regarding to DIN EN ISO/IEC 17020 for the inspection procedures in question or*

- *records of an on-site-audit performed by a competent auditor stating that the relevant requirements of the DIN EN ISO/IEC 17043 are fulfilled. Audits have to be regularly performed.*

The competent and comprehensive implementation of the audit must be clearly evident based on recordings.

Between the PT-provider and the subcontractor a binding contract must be concluded which contains at least the following details:

a. *exact designation of the contractual partner*
b. *confidentiality*
c. *exact description of the activities to be carried out and the prescribed specifications, e. g. for the production of proficiency test items*
d. *possibilities of audits by the PT-provider, if applicable with attendance of the accreditation body*
e. *exclusion of another subcontract*
f. *obligation that the relevant requirements of applicable standards are respected.*

In the contract with the subcontractor it must also be defined that the raw data which will not be handed over to the PT-provider, e. g. Calibration data or device books, have to be archived at least five years and have to be made available for the PT-provider on demand.

5.13.2 Technical records

If electronic records are captured and archived the PT-provider must establish regulations which ensure that the electronic archiving of documents fulfil the requirements on function and safety in the same way as conventional methods. This applies in particular to the warranty that archived documents and records are available at any time as well as for securing the authenticity of the documents, the confidentiality and permanent legibility.