

Swedac's policy for participation in proficiency testing and/or interlaboratory comparisons other than proficiency testing

Foreword

The document is aimed at accredited bodies such as:

Laboratories

- Testing, Calibration:
SS-EN ISO/IEC 17025:2018, clause 7.7.2, specifies that laboratories shall monitor their performance by comparing their results with those from other laboratories through participation in proficiency testing or other interlaboratory comparisons.
- Medical Testing:
SS-EN ISO 15189:2022 for clinical laboratories stipulates in clause 7.3.7.3 the equivalent requirement for participation in external quality assurance.

Inspection Bodies

- ISO/IEC 17020:2012 for inspection bodies specifies in clause 6.1 the requirement for effective monitoring. Proficiency testing can be a useful tool for demonstrating competence for certain types of measurements and can complement the witnessing of inspectors.
- In applicable cases, this document is also valid for inspection bodies.

PT Providers (PTP)

- Although ISO/IEC 17043:2023 does not specifically require proficiency testing and/or interlaboratory comparisons other than proficiency testing, laboratories performing testing or calibration are expected to comply with the requirements of ISO/IEC 17025:2017 and ISO 15189:2022 to ensure their results and competence.

Reference Material Producers (RMP)

- Although ISO 17034:2016 does not contain specific requirements for proficiency testing, producers of reference materials that perform testing or calibration are expected to comply with ISO/IEC 17025:2017 and ISO 15189:2022 to ensure their results and competence.
This means that those involved in the production of reference materials and PT Items must implement external comparisons (proficiency testing and/or interlaboratory comparisons) to ensure the accuracy and traceability of their testing or calibration results.

Biobanks

- SS-EN ISO 20387:2021 requires that biobanks use objective methods to ensure the comparability of the quality of biological materials.
This means that biobanks are subject to requirements to use external comparisons, such as proficiency testing, external quality assurance, or interlaboratory comparisons, to ensure quality and comparability in the handling and testing of biological material.

Terminology

Interlaboratory comparison (ILC) is design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2023, 3.4).

Proficiency testing (PT) is evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2023, 3.7).

External quality assessment (EQA) is evaluation of participant performance against preestablished criteria by means of interlaboratory comparisons (ISO 15189:2022, 3.10).

Policy

Swedac considers participation in proficiency testing schemes as a very important tool to demonstrate the technical competence of a laboratory and other organizations performing analysis activities.

Bodies (see above) applying for accreditation must have a plan to participate in relevant available proficiency tests and/or interlaboratory comparisons, and if possible, demonstrate their competence through participation before accreditation can be granted.

Calibration laboratories shall normally prove their ability to achieve the best measurement standards by participating in relevant calibration comparisons for the quantities and relevant measurands that they want to be accredited for.

Each accredited laboratory must define, in a specific plan, the level and frequency of their participation in proficiency testing schemes. This plan is to be based on a riskanalysis regarding, for example, testing volumes, staff, type of method and its complexity and robustness, equipment, calibration intervals, risks and opportunities associated with the laboratory activities etc. Attention should also be paid to other quality assurance activities, such as regular use of (certified) reference materials, repeated tests or calibrations with the same or other methods and re-testing or recalibration of archived objects, robustness of the metrological traceability chain, extent of validation and/or verification etc. The plan should be reviewed regularly and cover a time span of at least 4 years.

Ideally, all measuring techniques, parameters and products should be represented in proficiency testing. However, this can be difficult to achieve in practice and is not always financially defensible. Therefore, the laboratory should identify areas of technical competence and group measuring techniques, parameters and products/test types in sub-groups so that the result from a proficiency testing scheme can be correlated to the respective sub-group.

For practical guidance see EA-4/18, which can be found on the Swedac website.

Calibration laboratories should, when possible, within a four-year period have carried out comparisons for all of the quantities for which the calibration laboratory is accredited.

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There may be sectors where participation in proficiency testing can be difficult, e.g. due to the technical characteristics of the measurement, few laboratories and the lack of proficiency testing schemes. Participation in proficiency testing can in some cases only be possible for parts of the measurement undertaken. In these areas, the suitability of other quality assurance measures is paramount. The laboratory's frequency for participation in proficiency testing schemes must also consider any requirements from regulatory authorities or other interested parties.

The laboratory must have suitable acceptance criteria (e.g. those used by the organiser) and have documented procedures for investigating doubtful or incorrect results, and where necessary, take any corrective or preventive action.

Prior to accreditation and during ongoing inspections, Swedac assesses whether the plan for proficiency testing and/or interlaboratory studies is relevant and sufficient in relation to the scope, and whether the results meet the set objectives. If the laboratory cannot demonstrate its competence within a reasonable time, corrective actions will be requested.

Swedac encourages laboratories primarily to use the comparison programmes that meet the essential requirements set out in SS-EN ISO/IEC 17043 through accreditation, or to evaluate themselves whether the proficiency tests and/or interlaboratory comparisons meet the relevant requirements, see also EA-4/21 INF (Guidelines for the assessment of the appropriateness of small interlaboratory comparison within the process of laboratory accreditation). In Swedac's accreditation register on the Swedac website, www.swedac.se, one can search for organizers who offer proficiency testing programs. (Search term: proficiency testing). If a relevant comparison cannot be found here, you should expand your search, see for example www.eptis.org.

References

1. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
2. ISO 15189:2022, Medical laboratories – Requirements for quality and competence.
3. ISO/IEC 17020:2012, General requirements for the operation of various types of inspection bodies.
4. SS-EN ISO/IEC 17043:2023, Conformity assessment- General requirements for proficiency testing.
5. ISO 17034:2016, General requirements for the competence of reference material producers
6. ISO 20387:2018, Biotechnology - Biobanking - General requirements for biobanking
7. EA-4/18 G:2021, Guidance on the level and frequency of proficiency testing participation.
8. ILAC-P9:06/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.



Visiting address: Österlånggatan 5, 503 31 Borås
Adress: Box 878, 501 15 Borås



0771-99 09 00



registrator@swedac.se



www.swedac.se