Schweizerische Eidgenossenschaft
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Swiss Confederation

Federal Department of Economic Affairs,
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State Secretariat for Economic Affairs SECO
Swiss Accreditation Service SAS

Unclassified

SAS regulations on the participation of accredited bodies in proficiency testing

Document no. 330.ew

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1 Introduction

The standard ISO/IEC 17025 [1] requires that the laboratory shall have quality control procedures for monitoring the validity of tests results and that this monitoring shall be planned and reviewed. One of the tools to be used to fulfil this requirement is the participation in interlaboratory comparisons (ILC) and in proficiency testing (PT).

The standard ISO 15189 [2] requires that the laboratory shall participate in interlaboratory comparisons, monitor the results and implement correctives actions when relevant.

Therefore, SAS document 330 based on ILAC P9 [3] provides additional information.

Participation in interlaboratory comparisons or proficiency testing is therefore an important part of the accreditation process.

2 Scope

This document sets out the SAS requirements and recommendations on the participation in interlaboratory comparisons or proficiency testing in the accreditation process for the candidate or accredited bodies performing testing or calibration activities. These conformity assessment bodies (CABs) can be testing or calibration laboratories, inspection or certification bodies.

In the context of this document, «laboratories» implies all types of CABs.

3 Definitions and abbreviations

Proficiency testing [5]

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

Interlaboratory comparison [5]

Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

4 Strategy of participation in ILC/PT

It is the responsibility of the body (in general a laboratory) to establish its level and frequency of participation in ILC/PT. This shall be done after careful analysis of its other quality control measures (examples are given below). The participation shall be made dependent on the extent to which other measures have been taken and the level of risk presented by the laboratory (elements to be take into account in the risk analysis are given below).

Once the «level» and «frequency» of participation is established, laboratories shall develop a proficiency testing strategy, which takes into account the factors highlighted below. The extent and content of this strategy will depend upon the circumstances and scope of the individual laboratory. This strategy shall form part of the laboratories' overall quality control strategy.

The strategy shall cover, at least, one accreditation cycle, and this strategy is to be reviewed by the laboratory for its suitability on an annual basis, usually and most appropriate during the formal management review.

The strategy and the reviewing process will be evaluated by the assessment team in each assessment on site and recorded in the assessment report.

Elements to be taken into consideration when establishing the strategy of PT participation:

a) Other types of QC can include:

- Regular use of (certified) reference materials;
- Comparison of analysis by independent techniques;
- Participation in method development/validation and/or reference material characterisation studies;
- Use of internal quality control measures;
- Other inter/intra - laboratory comparisons e.g., analysis on blind samples within the laboratory.

b) Elements that can affect the level of risk presented by the laboratory:

- Number of tests/calibrations/measurements undertaken;
- Fluctuation of technical staff;
- Experience and knowledge of technical staff;
- Source of traceability (e.g., availability of (certified) reference materials, national standards, etc.);
- Known stability/instability of the measurement technique;
- Significance and final use of testing/calibration data (e.g., forensic science represents an area requiring a high level of assurance.).

It is acknowledged that it is unlikely to be feasible, both logistically and economically, that laboratories participate in PT schemes for every method included in the accreditation scope. Therefore, laboratories are expected to identify:

- groups of sets of measurement techniques,
- properties and products on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group.

These groups of sets of measurement techniques, properties and products are termed a «sub-discipline» or «area of technical competence» (see EA-4/18 G [4]).

5 Selection, use and interpretation of PT schemes

The European database EPTIS at www.eptis.bam.de is highly recommended as a search aid for special proficiency testing programmes. SAS sector committees can also recommend participation in specific PT schemes or programmes.

It is the responsibility of the laboratory to select the most appropriate PT provider. Laboratories are expected to participate in schemes that are proposed by competent PT providers. Also, required participation in distinct PTs may be another source to be considered.

PT providers that fulfil the requirements of ISO/IEC 17043 [5] are considered to be competent. Even though no formal multilateral agreement exists, SAS recognises the PT providers that have been accredited by ILAC full members.

If no appropriate PT provider is available and/or no adequate other quality control is available, the laboratory can organise or participate in bilateral (2 or a few laboratories) comparisons. However, these comparisons shall fulfil the relevant requirements of EA 4/21 INF [6].

Laboratories have to review and interpret their ILC/PT results, performance scores and if necessary, take corrective actions. Where relevant, laboratories can revise their performance score if the performance evaluation made by the PT provider is considered inappropriate (too strict/too narrow or too basic/too large).

Laboratories have to initiate an investigation for each unsatisfactory result and when the PT results indicate a potential problem (for example after a series of questionable results). The laboratory shall record each investigation made and the relevant corrective actions taken.

The assessment team shall check during assessments that the laboratory has reviewed its results and taken any action that was deemed necessary.

6 Specific rulings for various fields

Specific requirements or recommendations are provided in the annexes. These recommendations have been established and approved by the SAS sector committees.

7 References and literature

[1] ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories

[2] ISO 15189: 2012 Medical laboratories – Requirements for quality and competence

[3] ILAC-P9: ILAC Policy for Participation in Proficiency Testing Activities

[4] EA 4/18 G: Guidance on the level and frequency of proficiency testing participation

[5] ISO/IEC 17043: 2010 General requirements for proficiency testing

[6] EA 4/21 INF: Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

8 Annexes

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Annex 1 – Calibration laboratories

Calibration laboratories are required to develop and maintain a plan for the participation in ILC. The relevant technical areas and measurement principles shall be based on a risk analysis and defined in a plan. An ILC can cover different areas based on the same measurement principles. If no ILC providers are available for a particular area, bilateral comparisons with other laboratories or the national metrological institute (NMI) may also be recognized.

The results of ILCs are usually expressed, for example, with the EN[1] factor. EN factors > 1 are followed by corrective actions that are documented. Other evaluation methods, such as z-factor, are also possible.

[1] EN-Factor: $E_n = \left| \frac{x_{lab} - x_{ref}}{\sqrt{U_{lab}^2 + U_{ref}^2}} \right|$

E_n – FaktorNormalized Error
E_n - Faktor < 1 Comparison value successful

x_{lab}	Measurement value from the lab
x_{ref}	Measurement value from the reference lab
U_{lab}	Measurement uncertainty from the lab
U_{ref}	Measurement uncertainty from the reference lab

Annex 2 – Forensic analysis

2.1 Introduction

The in annex 2 summarized points concern testing in the field of forensic genetics, forensic chemistry and forensic toxicology. Also testing in crime scene investigation activities as far as systematic approaches or schemes are available either by ENFSI or by another forensic organisation not specifically mentioned in the annex.

NOTE: Subsequent cited bibliographic references can be adapted or upgraded according to the actual progress in the sector committee.

2.2 Terms and Definitions

ASTRA	Federal Roads Office (FEDRO)
EJPD	Federal Department of Justice and Police
CSCQ	Centre Suisse de Contrôle de Qualité / Swiss Center for Quality Control (PT provider)
SGRM / SSML	Swiss Society of Legal Medicine (SSLM)
ENFSI	European Network for Forensic Science Institute

2.3 Bibliographic references

Table: References

Technical Field	National Laws and Ordinances	Other Official Directives or Recommen-dations	Directives and Recom-mendation of National Organisations	Directives and Recommendation of International Organisations	Notes
Forensic Genetic	[1], [2]	--	[3]	--	--
Forensic Chemistry	--	--	[4]	[5]	--
Forensic Toxicology	--	[6]	[7], [8]	--	Ref. [7] only in French available.
Crime Scene Investigation Testing	--	--	--	[9]	Depending on the technical fields' different approaches for ILC/PT by technical sections of ENFSI.

[1] Verordnung über die Verwendung von DNA-Profilen im Strafverfahren und zur Identifizierung von unbekannten oder vermissten Personen (DNA-Profil-Verordnung) vom 3. Dezember 2004.

[2] Verordnung des EJPD über die Leistungs- und Qualitätsanforderungen für forensische DNA-Analyselabors (DNA-Analyselabor-Verordnung EJPD) vom 29. Juni 2005.

[3] Richtlinien der Sektion Forensische Genetik der SGRM: Richtlinien für die Durchführung von genetischen Abstammungsuntersuchungen (Datum des Inkrafttretens: 23.11.2019). Richtlinien zur internen Qualitätssicherung bei Spurenuntersuchungen mittels DNA-Untersuchungstechniken (Datum des Inkrafttretens: 23.11.2019); https://www.sgrm.ch.

[4] Fachgruppe Forensische Chemie: https://www.sgrm.ch.

[5] ENFSI Forensic Guidelines: PTs and CEs (https://enfsi.eu/about-enfsi/structure/working-groups/documents-page/documents/forensic-guidelines/).

[6] ASTRA, Weisung betreffend die Feststellung der Fahrunfähigkeit im Strassenverkehr vom 01.09.2004, see also http://www.astra.admin.ch.

[7] CSCQ, Médecin légale, alcool, drogues et médicaments, https://www.cscq.ch.

[8] Fachgruppe Forensische Toxikologie: https://www.sgrm.ch.

[9] ENFSI https://www.enfsi.eu/ and subsequent pages and links.

Annex 3 – Medical laboratories

Laboratories in human medicine

In Switzerland, the participation in interlaboratory comparisons (ILC) or proficiency testing (PT) is mandatory by Swiss law (federal act of health insurance, SR 832.10 article 58, and ordinance of health insurance (SR 832.102 article 77).

QUALAB (Schweizerische Kommission für Qualitätssicherung im medizinischen Labor/ Swiss commission of quality-assurance in medical laboratories) is the mandated organisation to implement the required quality control actions in laboratory medicine used so far also as an element in accreditation. The Swiss PT providers for medical diagnostics are accredited by SAS.

A current list (per year) of mandatory proficiency tests and additional information to the legal quality-assurance concept are published on the homepage of QUALAB (www.qualab.ch).

If a laboratory executes testing in a «sub-discipline» or «area of technical competence» (see 1.4) that is not covered by the mandatory PT, it is the responsibility of the laboratory to select an appropriate proficiency test or suitable alternative in this field.

During assessments, SAS checks the compliance of the results, the analysis and the arising corrective action(s) in the laboratories.

Laboratories in veterinary medicine involved in official animal disease diagnostics

For official animal disease diagnostics in Switzerland, the Food Safety and Veterinary Office (FSVO) recognizes laboratories that are organized by the state or privately. The Ordinance of Animal Disease (SR 916.401) asks among other things for accreditation and regular participation in interlaboratory comparisons (ILC) or proficiency testing (PT) as requirements for the above-mentioned recognition.

In addition, the FSVO designates reference laboratories for the diagnostic of specific animal diseases in Switzerland. One of the tasks of these laboratories represents the organization of specific ILC/PT taking into account the actual disease status in Switzerland as well as in neighbouring countries.

During assessments, SAS checks the compliance of the mandatory and voluntary ILC/PT results, the analysis and the arising corrective action(s) in the laboratories.

Annex 4 – Chemistry

The diversity of physical-chemical analysis (environment, food, pharmaceuticals, materials, substances etc.), makes it difficult to define more specific regulations than those listed in the general section. However, in order to present the range of performed proficiency testing in a comprehendible manner, the testing laboratory shall define its relevant technical scopes and record the frequency and regularity of participation in proficiency testing in a plan.

EA-4/18 G [4] provides case studies to illustrate how a laboratory might review their accreditation scope and thus derive the «sub-discipline» or «area of technical competence».

Competent authorities can prescribe participation in defined PT/ILC for certain areas. These must be followed by the accredited testing laboratories.

Annex 5 – Food - Biology

For official laboratories or laboratories assigned with official tasks, some requirements are in the regulation (Verordnung über den Vollzug der Lebensmittelgesetzgebung, SR 817.042).

In the sector committee Food (part Biology) rules were set. For microbiological procedures and parameters/characteristics in the food and water sector, there are regular offers of proficiency tests. The appropriateness of performance testing by proficiency tests is given for the microbiological methods, since the performance characteristic «absolute rightness» is not possible. A comparability is given at least with the external proficiency tests. So, performance tests of microbiological parameters must take place by means of external performance monitoring.

It is recommended that such a monitoring is done at least annually for each parameter.

Some important providers of proficiency testing in food and water microbiology are for example:

- Fera Science Ltd (FAPAS)
- LGC Axio Proficiency Testing
- Public Health England (FEPTU)
- DRRR Deutsches Referenzbüro für Ringversuche und Referenzmaterialien GmbH, muva Kempten.

Should the participation in a proficiency test not be possible due to lack of availability, the laboratory shall then take alternative measures (laboratory comparisons) to guarantee the comparability of the results.

For chemical analysis of food see above (Annex 4).

Annex 6 – Construction materials

For years, the association of accredited construction laboratories (VAB) and the association of construction laboratories (Robin) in Switzerland have been and are still regularly organising proficiency tests.

The SAS encourage the participation of the accredited laboratories in these national ILC/PT's. Besides these national initiatives other ILC/PTs fulfilling the purpose are welcome to be a base for external quality control (e.g., EPTIS or others international ILC/PTs).

If no PTs are available and no ILC's with another laboratory are possible, at least the requirements according to ISO/IEC 17025 Clause 7.7.1 shall be fulfilled.

Laboratories shall establish a concept for this in accordance with articles 1.4. and 1.5. of this document (see also Annex 7 for mechanical testing).

Annex 7 – Mechanical and non-destructive testing

Wherever possible, laboratories are required to seek out proficiency testing providers and programs for the concerned technical sectors accredited to ISO/IEC 17043 from internationally recognised accreditation bodies. The corresponding SAS accredited PT providers are published on its website.

Depending on the technical field, laboratories have the possibility to participate in PT programs organised by (national) professional associations (e.g., Swiss society for non-destructive testing) or recognised (public) institutions (e.g., EMPA - Swiss Federal Laboratories for Materials Science and Technology) when offering such services.

Finally, again depending on the technical field, laboratories can organise interlaboratory comparisons (ILC) on an ad hoc basis (see ISO/IEC 17025, chap. 7.7.2).

The following basics, which require or support the execution of proficiency testing, shall be observed if relevant:

a) National laws and ordinances;

b) Other official directives and recommendations in the mechanical field (e.g., from Federal offices, SAS);

c) Guidelines and recommendations of national organisations; technical regulation (e.g., professional associations, industrial organisations);

d) Guidelines and recommendations of international organisations (e.g., EU);

e) Standards (test or product standards).

Annex 8 – EMC, electrical safety and environmental simulation testing

In general, the regulations are laid down in the present PT concept of SAS. Hence, below only a few more specific rules to take into consideration for the scope of EMC:

The verification of control and correctness of the applied testing/measurement principles of the base standards, which are listed in the scope of validity, shall be fulfilled at least once per accreditation period (5 years) for all testing/measurement techniques (see art. 1.4).

The accredited body shall record the results, the analysis and the arising corrective action and report on any findings and possible improvement measures at the subsequent assessment / surveillance.

Comparison tests (such as ILC) are essential where surveillance of results with calibrated measuring instruments is not possible or where control of the influencing factors of the test object is problematic.

If adaptation of the measuring facility to the test object is not accurately established, and if this can lead to varying results, then comparison tests are required to really ensure that the chosen method produces comparable and reproducible results.

Else, alternative approaches shall be demonstrated to give adequate confidence. It must be recognised, that there are sectors where participation in ILC or PT may be difficult, due to the technical characteristics of the measurement and/or the lack of ILC or PT schemes, the low number of existing laboratories in the sector, etc.

Alternatively, to improve the quality level of the laboratories, an internal comparison can be performed and recorded (ISO/IEC 17025 – chap. 7.7.1). Following aspects have to be taken into account:

- is there a plan where the laboratory defines the frequency and level of the internal test;
- how the performance characteristics of a method have been evaluated;
- are there other methods available;
- have the results been compared internally with two or more test persons;
- are the results protocolled and have the measures been analysed?

Such comparison tests may also be performed within the testing laboratory, when two independent testing/measurement techniques are employed for the expected result.

The SAS principally favours the organisation of comparison measurements through a member of PEGESS (PEGESS: Prüfstellen-Erfahrungs-Gemeinschaft-für EMV, Sicherheit und Sachschutz) or through METAS (Federal Institute of Metrology: https://www.metas.ch/).

The sector committee and the SAS developed a specific guide «SAS Doc 335d».

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