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SAS regulations on the participation of accredited bodies in proficiency testing

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1. General

1.1 Introduction

The standard ISO/IEC 17025:2005 “General Requirements for the competence of testing and calibration laboratories” [1] (sub-clause 5.9) establishes 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 and in Proficiency Testing (PT).

The standard ISO 15189 : 2007 “Medical laboratories — Particular requirements for quality and competence” [2] establishes that the laboratory shall participate in interlaboratory comparisons and shall monitor the results and implement correctives actions when relevant.

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

1.2 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 bodies can be testing or calibration laboratories, inspection or certifications bodies.

In the context of this document, “laboratories” implies all types of bodies– i.e. testing, calibration and medical laboratories, inspection bodies, certification bodies.

1.3 Terms and abbreviations

Proficiency testing [3]
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

Interlaboratory comparison [3]
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

1.4 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 should be done after careful analysis of its other quality control measures (examples are given below). The participation should 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 (period between full reassessments), 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 effect the level of risk presented by the laboratory:
- Number of tests/calibrations/measurements undertaken;
- Turnover 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” (EA-4/18 [4]).

1.5 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. 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 have to fulfil the relevant requirements of ISO/IEC 17043.

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

1.6 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.

1.7 References and literature

[1] ISO/IEC 17025: 2005 General requirements for the competence of testing and calibration laboratories
[2] ISO 15189: 2007 Medical laboratories – Particular requirements for quality and competence
[3] ISO/IEC 17011 : 2004, Conformity assessment – General requirements for bodies providing accreditation of conformity assessment bodies
[4] EA 4/18 Guidance on the level and frequency of proficiency testing participation
[5] ISO/IEC 17043 : 2010 General requirements for proficiency testing

1.8 Annexes

Annex 1 – Calibration laboratories
Annex 2 – Forensic analysis
Annex 3 – Medical diagnosis
Annex 4 – Chemistry
Annex 5 – Food
Annex 6 – Construction materials
Annex 7 – Mechanical and non-destructive testing
Annex 8 – EMC, electrical safety or environment simulation testings

Annex 1 – Calibration laboratories

Assessments and re-assessments of calibration laboratories are always related to an interlaboratory comparison (ILC). This is done during the assessment and contains all physical quantities which will be or are still accredited. Normally the transfer instruments, with their known calibration results, are provided by metas (NMI). The inter comparison results are expressed by the EN factor. EN factors > 1 are followed by corrective actions under observation of SAS.

Further, inter comparisons are organised during the accreditation period for most physical quantities, but generally only on national level. Providers are the metrological departments of metas or others from sector committee calibration recognised national or international PT/ILC providers.

Annex 2 - Forensic Testing

2.1 Introduction

In the annex 2 summarized points concern testing in the field of forensic genetics, forensic chemistry, forensic toxicology. Also testing in crime scene investigation activities as far as systematic approaches or schemes are available either by ENFSI or other 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 Recommendations	Directives and Recommendation of National Organisations	Directives and Recommendation of International Organisations	Notes
Forensic Genetic	[1], [2]	--	[3]	--	--
Forensic Chemistry	--	--	[4], [5]	[6]	--
Forensic Toxicology	--	[7]	[8], [9]	--	Ref. [8] only in French available.
Crime Scene Investigation Testing	--	--	--	[10]	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 (Stand am 26. Juli 2005)).

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

[3] Genetik Richtlinien der Sektion Forensische Genetik der SGRM: Richtlinien der Sektion Forensische Genetik zu Abstammungsuntersuchungen, genehmigt am 19. November 2004; Richtlinie zur internen Qualitätssicherung bei Spurenuntersuchungen mittels DNA-Untersuchungstechniken genehmigt am 19. November 2004; http://www.sgrm.ch.

[4] Gruppe forensische Chemie SGRM – Pflichtenheft vom 2. März 2001.
[5] Ringversuche der Gruppe forensische Chemie der SGRM / SSML, Jahr 2003, „Auswertung vom 19. April 2005" as well as renewal years (available through SGRM / SSML).
[6] ENFSI QA-Subcommittee, Proficiency Testing Within ENFSI Drug Working Group, General Policy, Issue No. 001, Ref. DWG-PT-001, 06-04-2005.
[7] ASTRA, Weisung betreffend die Feststellung der Fahrunfähigkeit im Strassenverkehr vom 01.09.2004. see also http://www.astra.admin.ch
[8] CSCQ, Médecin légale, alcool, drogues et médicaments, http://www.cscq.ch .
[9] Pflichtenheft der Gruppe Toxikologie – in progress.
[10] ENFSI http://www.enfsi.eu/ and subsequent pages and links.

Annex 3 - Medical Examinations

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 organization to implement the required quality control actions in laboratory medicine used so far also as an element. in accreditation. The Swiss PT provider 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 http://www.qualab.ch.

If laboratory execute testing in an“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 in this field.

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

Laboratories in veterinary medicine

The Ordinance of Animal Disease (SR 916.401) ask for accreditation and regular participation in PT’s. as requirements for Federal recognition of these laboratories..

In Switzerland there are several reference laboratories for specific animal diseases that are designated by the Federal Office of Veterinary. One of the tasks of this laboratories is the organization of very specific ILC’s for particular animal diseases. There are periodical campaigns, the laboratories shall participate also taking into consideration the actual disease status of the country. .

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.

[1] SR 832.10, Bundesgesetz vom 18. März 1994 über die Krankenversicherung (KVG)
[2] SR 832.102, Verordnung über die Krankenversicherung (KVV) vom 27. Juni 1995
[3] SR 916.401, Tierseuchenverordnung (TSV) vom 27. Juni 1995

Annex 4 – Chemistry

The diversity of physical-chemical analysis (environment, food, pharmaceuticals, 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 testings in a comprehendible manner, the testing laboratory shall define its relevant technical scopes and record the frequency and regularity of participation in proficiency testings in a plan.

A relevant technical scope may be, for example, a sampling procedure including the testing procedure, a single testing procedure or several testing procedures that are all based on the same measuring principle.

Limited participation in proficiency testing is tolerated if the laboratory can provide alternative verification of the comparability of its results (e.g. certified reference material).

The laboratories shall hold the results and analyses of the performed proficiency testings readily available for the assessments. In the case of unfulfilled proficiency testings, the laboratory shall present the cause analysis and imposed corrective action, to demonstrate that all steps have been taken to achieve comparable results.

Annex 5 – Food

Some important providers of proficiency testings in food microbiology include recognised by associations are:

1. Central Science Laboratory (UK) has several schemes:
   Food chemistry testing: http://www.fapas.com/fapas.cfm
   Food microbiology scheme: http://www.fapas.com/fepas.cfm
   GMO analysis: http://www.fapas.com/gemma.cfm
   Water proficiency testing: http://www.fapas.com/leap.cfm

2. Health protection agency (UK): http://www.hpa.org.uk/srmd/services/eqas.htm, mainly microbiology: food, legionella and water

3. LGC Standards (UK): http://www.lgcpt.com with a large choice of schemes.

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

Annex 6 – Construction materials

The sector committee and the SAS responsible developed a specific guide “SAS Doc 326”.

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

The SAS encourage the participation of the accredited laboratories in these national ILC/PT’s. Besides these national initiative other ILC/PT’s fulfilling the purpose are welcome to be a base for external QC (e.g. EPTIS or others EA selected ILC/PTs).

The laboratories are free to participate alternatively or as well in other experiments. They shall establish a concept for this in accordance with articles 1.4. and 1.5. of the general regulations.

On the SAS website, under sector committee construction, an informal list shows some current planned proficiency or comparison tests.

Annex 7 – Mechanical and non-destructive testing

The SAS offers, on its homepage under SAS sector committee “mechanical and non-destructive testing”, an informal list of comparison tests organised by the testing laboratories.

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

a) National laws and ordinances;
b) Other official directives and recommendations in the mecanical 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 testings

In general, the regulations are laid down in the 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.

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 favoured the organisation of comparison measurements through a member of PEGESS. In addition, reference is also made to the EPTIS database.

PEGESS: Prüfstellen-Erfahrungs-Gemeinschaft-für EMV, Sicherheit und Sachschutz