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Guidelines for Accreditation of the Swiss Laboratories Performing Forensic Toxicological Analyses

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Preface

This revision of the guidelines is based on the work of the ad hoc working group forensic toxicology of the Sector Committee of the Swiss Accreditation Service (SAS) and was due to the update of the standard ISO / IEC 17025:2005.

These guidelines describe the particularities and requirements in the main activities of forensic toxicology and are based in most parts on the references stated on chapter 2. The guidelines can only be used in combination with those cited references. Requirements that are explicitly stated in the standard ISO / IEC 17025:2005 or in the ILAC guidelines for forensic science laboratories and that can be applied without any changes in the field of forensic toxicology are not mentioned in this document in full length. Therefore, the guidelines refer in these particular points to the corresponding documents.

The guidelines help the assessor team to interpret requirements and obtain a harmonised basis for the assessment of laboratories of forensic toxicology. The quality system (Q-system) of the laboratory shall contain acceptable implemented solutions for the various points. Together with appropriate check lists these guidelines may give to the staff of these laboratories helpful hints and guidance for the development of their own adequate Q-system but do not cover all aspects of forensic toxicology. During an assessment visit, the transformation of the various stated requirements into practice will be checked. If some elements of the standard ISO / IEC 17025, parts of it or explicitly stated requirements in these guidelines are not considered in the Q-system of the laboratory, it will lead to corrective actions or measures that shall be initiated by the laboratory to obtain accreditation.

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Guidelines for Accreditation of the Swiss Laboratories Performing Forensic Toxicological Analyses

1. Scope

(ISO / ILAC pt. 1, SOFT, Rules SSLM)

Forensic toxicology consists in the determination by scientific analyses of pharmacologically active substances and their metabolites in man and the interpretation of the results to support the application of legal and administrative measures for post-mortem and human behaviour investigations.

Activities in the Forensic Toxicology Laboratory

Forensic toxicology work involves the examination of a wide range of items and substances. The following activities are defined by the Toxicology Section of the Swiss Society of Legal Medicine (SSLM) and may be encountered in the Swiss forensic toxicology laboratories. Other activities in those laboratories are possible.

A) Alcohol and Driving

This activity includes the analysis of blood alcohol in traffic cases. Laboratories working in this field have to be approved by the Swiss Federal Roads Authority (FEDRO).

B) Driving under the influence of drugs

This activity implies the analyses of drugs and other psychoactive substances in blood and urine of suspected drivers. Also in this field laboratories have to be approved by the Swiss Federal Roads Authority (FEDRO).

C) Human-behaviour Forensic Toxicology

In this activity the absence or presence of drugs and their metabolites, alcohol and other chemicals is determined in blood, urine or other biological specimen(s) to demonstrate prior use of drug(s) and to evaluate their role in modifying human performance or behaviour. Typical examples are:

a. Drug detection at the working place
b. Involuntary intake of drugs and submission by chemicals
c. Poisoning
d. Misuse or abuse of substances and drugs
e. Doping
f. Toxicological examination of specimen of evidence #

D) Post mortem Forensic Toxicology

In this activity the presence or absence of drugs and their metabolites, chemicals and volatile substances, gases, metals, and other toxic compounds is determined in human fluids and tissues to evaluate their role as a determinant or as a contributory factor in the cause and manner of death. Such situations can be:

a. Fatal drug(s) intoxication
b. Prior drug abuse
c. Suicide by drug exposure
d. Poisoning
e. Criminal offence
f. Exclusion of intoxication
g. Toxicological examination of specimen of evidence #

For the analyses of pharmaceutical substances not in relation to the forensic toxicology cases: see "*Leitfaden zur Akkreditierung von Schweizer Prüflaboratorien zur Durchführung Forensischer Drogenanalytik, Nr. 318.d Ausgabe August 2005 Rev. 01*

2. Normative references

(ISO / ILAC pt. 2)

- General requirements for the competence of testing and calibration laboratories (ISO 17025:2005). In the text referred as “ISO”.
- Guidelines for Forensic Science Laboratories, draft 1.6, February 2001 - ILAC/TAI(01)05. In the text referred as “ILAC”.
- Forensic Toxicology Laboratory Guidelines, SOFT/AAFS, version 2006. In the text referred as “SOFT”.
- Rules of the Toxicology Section of the Swiss Society of Legal Medicine (SSLM), dated November 18th, 2006. In the text referred as “Rules SSLM”.
- Empfehlungen zur Validierung von Analysenmethoden in der Forensischen Toxikologie, dated November 7th, 2002, recommendations of the Toxicology Section of the Swiss Society of Legal Medicine (SSLM). In the text referred as “Validation SSLM”.
- Weisungen betreffend die Feststellung der Fahrunfähigkeit im Strassenverkehr, dated 1st september, 2004, Swiss Federal Roads Authority (FEDRO), in the text referred as „Guidelines FEDRO“.
- Eurolab, Guidance for the Management of Computers and Software in Laboratories with Reference to ISO / IEC 17025:2005, Technical Report No 2/2006, October 2006, in the text referred as “Eurolab Technical Report No 2/2006”.

3. Terms and definitions

(ISO / ILAC pt. 3)

Specific definitions are given within this text.

4. Management requirements

(ISO / ILAC pt. 4)

[4.1 – 4.12]
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

4.13. Control of records

[4.13.1 General]
[4.13.1.1 – 4.13.1.4**]**
(ISO / ILAC pt. 4.12.1)
The aim of this requirement is that the general laboratory performing forensic toxicology shall have documented procedures to ensure that it maintains a co-ordinated record relating to each case under examination. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the whole test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for sampling, performance of each test and/or calibration and checking of results. In general, the records required to support conclusions shall be such that, in the absence of the analyst, another competent analyst

could evaluate what had been performed and interpret the data. Copies of reports have to be retained together with other records relevant to the case for the duration required.

[4.13.2 Technical records]
[4.13.2.1]
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

[4.13.2.2]
Every document of relevance in the case record shall be traceable to the analyst and where appropriate, to a uniquely identified case. It shall be clear from the case record by whom and when the analysis was performed.

Remark: Pagination using a page numbering system which indicates the total number of pages is not systematically applicable for all records generated by forensic toxicology laboratories. It has to be clearly specified in which cases pagination has to be applied.

Where appropriate, observations or test results shall be preserved by photography or electronic scanning (e.g. thin-layer chromatography results). Clearly traceable photocopies of originals, tracings or hand-drawn facsimiles may also be suitable.

[4.13.2.3]
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

4.14. Internal audits
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

4.15. Management reviews
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

5. Technical requirements
(ISO / ILAC pt. 5)

5.1. General
Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. The complex organisation of Legal Medicine with its different fields (forensic medicine, forensic genetics, forensic toxicology, forensic chemistry) requires a good arrangement between these divisions.

5.2. Personnel
(ISO / ILAC pt. 5.2, SOFT and Rules SSLM)
[5.2.1]
The head of the laboratory shall possess a degree in chemistry, biochemistry or pharmacy with preferably a corresponding doctoral degree and gained experience during at least five years of full-time laboratory work in the corresponding activities of forensic toxicology. Further qualifications include the title „Forensischer Toxikologe SGRM / Toxicologue forensique SSML“ or an equivalent education recognised by the Swiss society of legal medicine (SSLM). Exceptions can be accepted by the SSLM.

[5.2.2]
The head of the laboratory shall have documented training and/or experience in the forensic applications of analytical toxicology (such as court testimony or expert reporting, research

and participation in continuing education programs). Because forensic toxicology involves legal issues, the head of the laboratory shall also have knowledge of evidentiary procedures that apply when toxicological specimens are acquired, processed and stored, and when toxicological data are submitted as part of a legal proceeding.

[5.2.4]

The laboratory's management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. It is responsible for:

- Ensuring that his staff is adequately trained and experienced to conduct the work of the laboratory.
- Maintaining the competency of laboratory staff by monitoring their work performance and verifying their skills.

The training and experience have to be documented. The job description shall reflect the duties and professional skills of the personnel.

[5.2.5]

The range and type of duties of laboratory personnel will vary according to the size and scope of the laboratory. It is recommended that each laboratory should have:

- A person with the title of deputy head of the laboratory, who has sufficient training and experience to be familiar with all administrative and testing procedures. He or she may supervise the work of all laboratory staff, and is capable of performing full scientific review of all test data, and of acting for the head of the laboratory in his or her absence. It is recommended that such individuals should have an equal qualification as the head.

- One or more laboratory technicians who are capable of performing a variety of test procedures for alcohol, drugs and other chemicals in biological fluids. Such individuals shall have at least a nationally recognised laboratory technical degree and be experienced in analytical toxicology.

Since forensic toxicology laboratories handle controlled substances and generate results essential to the criminal justice system, the head of the laboratory, to the extent practical or permitted by law, should exert reasonable efforts to ensure that all personnel meet high ethical and moral standards.

5.3. Accommodation and environmental conditions

(ISO / ILAC pt. 5.3, SOFT)

[5.3.1]

Laboratories need to be aware of the risk of laboratory contamination, and shall demonstrate appropriate measures to avoid any such occurrence. Laboratories working in the fields of forensic toxicology and bulk drug analysis have to separate those two areas.

[5.3.2]

Specimens need to be stored in a secure manner. The storage conditions shall be such as to prevent loss, deterioration and contamination, and to maintain the integrity and identity of the evidence. Any transfer of specimens or any aliquots removed for analysis or their controlled storage or disposal shall be documented.

[5.3.4]
Access to the area of the laboratory is limited. Visitors shall be escorted and noted in a log-book upon entry and departure from the laboratory, recording the time, date and person to be visited.

[5.3.5]
The laboratory has to have documented procedures concerning safety issues or a safety manual that addresses at a minimum the following issues:

- Specimen handling, including the handling of infectious material and the disposal of biological specimens
- Handling and disposal of solvents, reagents and other chemicals in the laboratory
- Handling and disposal of any radioactive materials used in the laboratory
- Handling and disposal of laboratory glassware
- Responses to personal injuries and spillage of biological specimens, chemicals, solvents, reagents or radioactive materials
- Regulation governing dress (e.g. laboratory coats and safety glasses), eating, drinking or smoking in the laboratory
- Cleaning and housekeeping of premise

5.4. Test and calibration methods and method validation

(ISO / ILAC pt. 5.4, SOFT, Validation SSLM, Guidelines FEDRO)

[5.4.1 General]
All analytical procedures used by a forensic toxicology laboratory shall be validated before being used on casework. Methods may be validated e.g. by comparison with other established methods. Certified reference materials (where available) or other materials of known characteristics are strongly recommended. The head of the laboratory is responsible for the extent and the well performance of the validation.

In general, all test methods can be divided into two classes:

A) Screening methods
Biological samples are screened for pharmacologically relevant compounds. If one or more substances can be identified, a second, independent analysis is usually needed to confirm the findings of a toxicological screening. Screening methods include e.g. immunochemical tests, chromatography or electrophoretic methods.

B) Confirmational methods
In order to obtain qualitative or quantitative proof of the existence or content of a substance in a biological sample, confirmatory tests shall be accomplished. Examples of instrumentation with confirmation capability are:

- Gas chromatography (GC) with two different separation columns and independent detectors
- Gas chromatography-mass spectrometry (GC-MS)
- Liquid chromatography with UV-Vis spectrophotometric or diode array detection (HPLC-UV-Vis-DAD)
- Liquid chromatography-mass spectrometry (LC-MS)
- Gas or liquid chromatography with two ore more-dimensional mass spectrometry (GC-MS/MS, GC-MSn, LC-MS/MS, LC-MSn).

In validating test methods, the following issues (among others) may need to be determined, as appropriate:

- Selectivity
- Linearity
- Working range
- Recovery
- Accuracy
- Repeatability
- Laboratory accuracy
- Reproducibility
- Limit of detection (LOD)
- Limit of quantification (LOQ)
- Ruggedness

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

Records of all in-house validations shall be maintained for future reference.

[5.4.2 Selection of methods]
Where a laboratory introduces a new method, it shall first demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure. This is part of the method validation.

[5.4.3 Laboratory-developed methods]
All methods shall be fully documented and validated in the above sense including procedures for quality control. Wherever possible, certified reference materials (CRMs) should be used.

[5.4.4 Non-standard methods]
When infrequently performed tests or analyses are concerned, re-verification of the good performance of the tests is first done by the use of an appropriate reference material, followed by replicate testing or analysis of the real sample(s).

Remark: This helps the laboratory staff to gain better skills before using infrequently performed tests for analysis of real samples.

[5.4.5 Validation of methods]
No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

[5.4.6 Estimation of uncertainty of measurement (confidence interval)]
In traffic-related cases the FEDRO has introduced harmonized measurement uncertainties (confidence intervals)

<u>For alcohol and driving:</u>

± 0,05 g/kg	for mean values ≤ 1,00 g/kg
± 5% of the mean value	for mean values > 1,00 g/kg

<u>For driving under the influence of drugs</u>:
± 30 % of the mean concentration in whole blood
Based on the results of the external quality controls (proficiency tests) of the last years

In the activities of Human-behaviour Forensic Toxicology and Post mortem Forensic Toxicology the Toxicology Group of the SSLM has proposed a measurement uncertainty of 30 % of the mean value of the measurement in all biological samples.

5.5. Equipment

(ISO / ILAC pt. 5.5)

[5.5.1]

As part of a quality system, all laboratories are required to operate a program for the maintenance and calibration of equipment used in the laboratory. The equipment used in a forensic toxicology laboratory is diverse and will range across a number of different scientific and technical disciplines. In most areas equipment may be categorised into:

a) General service equipment not directly used for making measurements, e.g. hot plates, stirrers, centrifuges, non-volumetric glassware, refrigerators, heating ovens.
b) Small measuring equipment with direct relation to the test result, e.g. thermometers, balances, volumetric glassware, pipettes, pH-meter.
c) Measuring instruments, e.g. chromatographs and electropherometers, spectrometers and spectrophotometers, and the combination thereof.
d) Computers and Computer Networks

[5.5.2]

Software from internationally accepted companies like Microsoft does not need to be validated, when no significant changes or programming (large macros, external routines etc.) were made. Professional data acquisition and treatment software being part of the analytical instrument does not need validation either. The laboratory shall be concerned to get all relevant validation data from the provider of the equipment. On the other hand changed or custom-made software needs validation.

Remark: See also Eurolab, technical report No 2/2006 as an aid to laboratories when they managing the use of software and computers with respect to the requirements of ISO / IEC 17025:2005.

[5.5.3]

General service equipment will typically be maintained by visual examination, safety checks and cleaning as necessary. Calibrations or performance checks will only be necessary where the equipment setting can significantly affect the test or analytical result (e.g. temperature of a refrigerator for storing reference material).

Regular calibration, cleaning and servicing shall be performed on small measuring equipment. All service and maintenance work shall be documented. The handling of this type of equipment should be documented, if manufacturers manuals and documentation are insufficient.

[5.5.4 – 5.5.5]

(ISO / ILAC pt. 5.5.5)

Correct use combined with periodic servicing, cleaning and calibration will not necessarily ensure that a measuring instrument or detection system is performing adequately. Therefore, where appropriate, periodic performance checks shall be carried out and predetermined limits of acceptability shall be assigned. The frequency of such performance checks will be determined by past history and should be based on need, type and previous performances of the equipment. All service and maintenance work shall be documented. The handling of this type of equipment shall be documented, preferably for each instrument. The manual shall also describe the actions to be taken in case of system failure. Measuring equipment failing routine checking cannot be used for further analyses, until the system is repaired, checked and re-admitted for use.

Computers and data processors that generate raw data shall be protected from data loss, unwanted data manipulation and theft. Integrity of data storage has to be proven.

5.6. Measurement Traceability

(ISO / ILAC 5.6)

[5.6.1 General]

No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

[5.6.2 Specific requirements]

Equipment used in forensic toxicology laboratories may be sub-divided into general classes depending on the type of calibration required:

a), b) and c) No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

[5.6.3 Reference standards and reference materials]

No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

If a reference substance (certified or not) cannot be obtained, quantification of this substance is impossible.

Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes (e.g. results of a screening analysis) shall be fully documented, uniquely identified and properly controlled. Reference standards and reference materials shall at any time be kept separated from case material.

5.7. Sampling

(ISO / ILAC 5.7)

[5.7.1 – 5.7.3]

The selection of sample material and the method of analysis are important parts of the forensic toxicology process. In the area of forensic science, emphasis is placed on the competence of all staff. Their training in these activities is therefore of prime importance. Laboratories shall ensure that there are documented procedures and training programs to cover this aspect of their work and that detailed competency / training records are kept for all staff involved.

All sampling shall be performed by trained personnel (e.g. physicians, pathologists, medical examiners, justice authorities, laboratory personnel).

5.8. Handling of test and calibration items

(ISO / ILAC 5.8, SOFT, Guidelines FEDRO)

[5.8.1 – 5.8.4]

Forensic toxicology laboratories shall assure that the samples analysed and reported on were the ones submitted to the laboratory beyond reasonable doubt. They shall, therefore, ensure that the proper “chain of custody” is maintained.

Remark: The traceability of all activities from the receipt, preparation, proper analyses, report of the results to the storage or disposal of the samples, shall be guaranteed.

5.9. Assuring the quality of test and calibration results

(ISO / ILAC 5.9)

[5.9.1 – 5.9.2]

No additional interpretation of this clause for laboratories performing forensic toxicology is necessary.

5.10. Reporting the results

(ISO / ILAC 5.10, SOFT, Guidelines FEDRO)

[5.10.1 – 5.10.3]

Reporting of results shall include all information necessary to identify the case and its source, and should bear test results and the signature of individual(s) responsible for its contents.

These informations should include:

1. Name and/or identification number
2. Laboratory identification number
3. Name of the client
4. Client's identification number
5. Date submitted
6. Date of reporting
7. Specimens tested, including date and time of sampling
8. Test methods
9. Test results
10. Signature of approving individual(s)

Although most forensic toxicology reports are confidential and often sensitive in content, some jurisdictions may treat the report as an official public document. For any confidential result or other data, every precaution should be exercised to ensure that the properly authorized person receives the information. Each laboratory shall formulate its own policy for retention or release of information and for response to requests for its documentation.

[5.10.5 Opinions and interpretations]

Terminology in reports

1. "Positive" or "Detected" indicates that a particular substance has been identified in accordance with the laboratory protocols. "Negative", "Not detected", or "None detected" has been generally used to indicate the absence of analyse or analyses. "None detected" is preferable. This indicates that particular substances were absent within the limitations of the test(s) performed.

2. Tests may be described in a number of ways, individual chemical entities, groups or classes of chemicals or combinations of drugs or chemicals. A description of the entity shall appear in the laboratory's standard operating procedure manual. This description shall include the limitations of the test, such as the drugs included, the limit of quantification, cut-off of the drugs included, cut-off concentrations (if applicable) or other terms to describe the lowest concentration reliably measured and reported in the specimen.

3. There may be both qualitative and quantitative results on a report. Qualitative results shall be indicated by naming the tested substance followed by the term "positive" or "none detected". The term "trace" should not be used in the report. No quantitative value shall be reported when an immunological or other initial testing procedure were used, unless the procedure has been appropriately validated by parallel studies with a reference quantitative method.

4. Units shall comply with generally established nomenclature used in the field. Preferred units are ng/mL, mg/L, µg/L, mg/kg for fluids and tissues. Ethanol shall be reported as promille (gram per kilogram).

In traffic cases the FEDRO demands a special reporting:

For alcohol and driving:

Mean value	≥	0,10 g/kg:	mean value and confidence interval
Mean value	<	0,10 g/kg:	< 0,10 g/kg (beneath the defined limit)

For driving under the influence of drugs:

Drugs with limits

Drug not detectable or			beneath the defined FEDRO limit
Value	<	limit:	
Value	≥	limit:	measured value

Substances without limits measured value

[5.10.6 Test results obtained from subcontractor]

(ISO / ILAC pt. 4.5)

Results of tests of a subcontracted laboratory may be incorporated into the laboratory's final report, but shall be clearly indicated as such.

[5.10.7 Electronic transmission of result]

For electronic transmission of result see also Eurolab, technical report No 2/2006 as an aid to laboratories when they managing the use of software and computers with respect to the requirements of ISO / IEC 17025:2005.

[5.10.8 Format of reports]

Preliminary report

A report may be issued before the final report has been prepared. This report should have the same identifying information as the final report but be limited to the tests performed by that date.

A clear statement of the preliminary report is necessary indicating that the results of this report are still indicative and will be followed by a validated final report.

Final report

The final report contains all relevant results und an interpretation thereof. If explicit questions were asked by the court or by a client, then the answers need to be made within this final report. The final report should, if applicable, contain a list of all preliminary reports concerning this case.

[5.10.9 Amendments to test reports]

Supplemental or addendum report

After a final report has been issued, it may be necessary to perform additional tests, in which case an addendum or revised report should be issued. An addendum may be created to provide the results of the additional tests. Such a report has to contain the same identifying information as the original report.

Oral reporting

Occasionally, it may be necessary to provide information on a report to a police or other external agency. In such situation, the results may be transmitted by telephone. The individual has to be appropriately identified. A final report is always required. A conversation protocol is strongly recommended.

Corrected report

After the final report has been issued it may be necessary to correct an error, typographical or other, in the final reports. This report has to be clearly labelled as corrected and contain the same identifying information as the final report.

Release of reports

There should be a written procedure for any kind of reporting to the client.

5.11. Other requirements

Each laboratory is aware of State and/or Federal Regulations that may exceed minimum standard established on the basis of the above guidelines.