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Legal Framework

Prum Convention



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The Prüm convention, a treaty signed on May 2005 by Austria, France, Belgium, Germany, Luxembourg, Netherlands and Spain has been adopted to enable the signatories to exchange data regarding DNA and fingerprints.

The Convention is open to all members of European Union



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The Decision of UE 2009/905/GAI has established

- in order to guarantee the analytical data produced in each country
- the accreditation of laboratories dealing with forensic evidences





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ILAC G-19 Modules in a Forensic Science Process



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The guide in a single document deals with the forensic process as a whole providing common guidance for both ISO /IEC 17025 and ISO /IEC 17020

In fact not always there is a clear and consistent distinction in forensic practice between the activities conducted at a scene of crime and those conducted in a forensic laboratory, nor is there always a clear and consistent distinction in the administrative location of personnel involved in the activities





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ISO/TC 272 Forensic sciences

- About
- Contact details
- Structure
- Liaisons
- Meetings
- Tools

Secretariat: SA
 Secretary: [Ms Monja Korter](#)
 Chairperson: Dr. Linzi Wilson-Wilde until end 2017
 ISO Central Secretariat contact: [Mrs Mary Lou Pelaprat](#)
 ISO Editorial Programme Manager: [Mrs. Laura Mathew](#)
 Creation date: 2012

Scope:

Standardization and guidance in the field of Forensic Science. This includes the development of standards that pertain to laboratory and field based forensic science techniques and methodology in broad general areas such as the detection and collection of physical evidence, the subsequent analysis and interpretation of the evidence, and the reporting of results and findings.

Excludes

- o Generic quality management standards dealt with by ISO/TC 176;
- o Conformity assessment guidelines dealt with by the ISO committee on conformity assessment (CASCO).

Total number of published ISO standards related to the TC and its SCs (number includes updates):	0
Participating countries:	20
Observing countries:	13

ILAC G19:08/2014

Modules in a Forensic Science Process

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Accreditation bodies can choose, as appropriate, to have accreditation programs which are based on ISO/IEC 17025 and/or ISO/IEC 17020 for different parts of the forensic science process.

The accreditation body should clearly describe which standard they intend to use for which parts of the forensic science process and ensure that this is made clear to any organizations applying for accreditation. Appropriate applications of ISO/IEC 17020 and ISO/IEC 17025 should be made by accrediting bodies based upon the presence or absence of testing in the segment of the forensic science process in question.





Competence

Both ISO/IEC 17025 and ILAC G 19 have strong requirements for all staff working in the forensic unit.

Management or responsible persons dealing with forensic evidences shall be able to demonstrate with objective evidence that all personnel are competent, by carrying out assessments of their knowledge and skills against defined criteria.

In assessing the competence of an individual the forensic unit shall ensure that where appropriate staff have relevant understanding of the technology behind the crime e.g. firearms, and the technology used to investigate the crime e.g. fingerprints, DNA profiling, blood pattern analysis.





Competence

Training record shall be maintained up to date
and shall include academic and professional
qualification and courses attended





Customer and client

ILAC-G19:08/2014 Modules in a Forensic Science Process

2.6 Customer

The customer is normally the organization and/or a person asking the forensic unit to perform all or a specific part of the forensic science process. This also includes the term '**client**'. This may be an internal customer. If work is requested via legal mandate (e.g. court order) or if the results of examination/testing are to be provided to a member of the judicial system, then **the judicial system may be considered to be the customer.**





ILAC-G19:08/2014

3.5 Records

The forensic unit shall have documented procedures to create and maintain records relating to each case under investigation. The information that is to be included in case records shall be documented appropriately and may include, but not be limited to, records of any communication with the customers (verbal or written), contract review, examination and testing requested and agreements with customer, exhibit receipts, descriptions of exhibits including packaging and seals, subpoenas, records of observations and test/examination results, reference to procedures used, diagrams, printouts, photographs, videos.





Contamination

ILAC-G19:08/2014 Modules in a Forensic Science Process

2.2 Contamination

Contamination is the undesirable introduction of substances or trace materials to exhibits at any point within the forensic science process.



Contamination prevention guidelines			
DOCUMENT TYPE :	REF. CODE:	ISSUE NO:	ISSUE DATE:
POLICY	ENFSI DNA WORKING GROUP	001	November 2010

Recommendations for Experimental design /set up

- ◆ Where possible, upon submission and before the DNA extraction stage, items for examination and sampling should be separated into high yielding (e.g. semen, tissue, blood) and low yielding DNA categories (e.g. items of skin contact, handled items). Low DNA yielding items should be sampled first and those yielding high quantities of DNA should be sampled last.
- ◆ Blank/negative controls will be used for every series of experiments.
- ◆ Separate batches must be processed for reference and crime scene samples.
- ◆ Intra and inter-batch contamination checks should be done.
- ◆ Sample results should be tested against the elimination database.
- ◆ Where possible, reagents should be divided and stored in as small aliquots as possible.





Data interpretations

In forensic field in many cases it would be very hard for the customer a clear understanding of data without opinions and interpretations.

The accreditation body must have a policy about accreditation of opinions and interpretations.





Accreditation of opinions and interpretation

The AB cannot grant accreditation for the opinion or interpretation produced

The accreditation shall be granted for the competence of and the process by which CABs are arriving at the opinions and interpretations made





Competence required for opinions and interpretations

Criteria for qualification shall be established and will be different according to situations.

If the level of opinion and interpretations concerns the use of the results an extensive qualification is needed

Qualification records will include :Experience in particular sector, Full qualifications record detailing career to date, Continuing Professional Development records (CPD) to demonstrate how the individual has kept up to date with changes in the particular sector for which opinions and interpretations are given, Examples of past work in the required field of expertise





EA and opinions and interpretations

EA has recently issued a new document, EA-INF/13 :2015, to promote harmonization between accreditation bodies on how opinions and interpretations should be assessed and how the accreditation of opinions and interpretations may be expressed and communicated to potential customers





Opinion and interpretation

If AB grant accreditation for opinions and interpretations, in accreditation document must be clearly stated the field in which opinion and interpretations are accredited .

For examples opinion and interpretation may be linked to some particular tests (matrices, parameters, methods)





ILAC-G19:08/2014

The type and amount of information required in the report may depend on the legal system. **However, in all cases, there shall be a clear indication of which parts are background information, which are facts and which are interpretations or opinions.**

.....

The forensic unit shall have a procedure and criteria to decide when and to what extent a **technical review** of a report needs to be performed.

Technical review should be performed by a qualified person with the appropriate competence to confirm the validity of the results. Conclusions shall be properly qualified.





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ENFSI

In 1992 the directors of Western European governmental forensic laboratories agreed that they should hold regular meetings to discuss topics of mutual interest. At the first meeting in 1993 in Rijswijk (The Netherlands) 11 laboratories were represented. It was agreed that membership of ENFSI would be open to countries from the whole of Europe

ENFSI is recognized as a pre-eminent voice in forensic science worldwide by ensuring the quality of development and delivery of forensic science throughout Europe. It will therefore strengthen and consolidate ENFSI, expand the membership throughout Europe while maintaining the development and credibility of ENFSI, establish and maintain a working relationships with other similar organizations, encourage all ENFSI laboratories to comply with best practice and international standards for quality and competence assurance Activities.



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ILAC News - Issue 47 | April 2015

International Updates | Regional Cooperations | Accreditation Updates | Stakeholder News

From the Secretariat

World Accreditation Day 2015
Secretariat Update

Regional Cooperations

AFRAC Update
News from ARAC
IAAC Activities

International Updates

News from BIPM
Promoting accreditation at the WTO Annual Conference
Public sector website launched
UNIDO - Quality Infrastructure Project

Accreditation Updates

Cofrac - A new online search engine
News from CGCRE
OAA - Dairy Laboratory Accreditation
News from PCA
Great News from ema!
News from BAB
News from AERSSC,

« Back

ENFSI - The European Network of Forensic

20 Years of Cooperation
by Wim Neuteboom and Terje Kjeldsen

Introduction

The European Network of Forensic Science Institute (hereinafter referred to as ENFSI) is this year celebrating its 20th anniversary.

It became a member of ILAC in 2006. The underlying philosophy was that it was in the interest of ENFSI to have close cooperation with this prominent organisation specialised in quality assurance topics in order to establish a common standard in European forensic science and to enhance the general level.

In this article, an overview of the history, aims and structure of ENFSI is presented.

It is obvious that forensic laboratories will be able to do a better job if first responders and crime scene officers have a high degree of forensic awareness. An investigation starts at the crime scene and this step - in terms of searching, collecting, and storage of physical evidence - is crucial for the success of later investigations at the forensic laboratory. Crucial elements in this are to have quality systems and guidelines assuring that evidence is treated the same way in all stages of the juridical process from the scene of the crime to the court.

But it's also important in today's globalised way of living that individuals are given the same treatment and a fair trial notwithstanding when or where in the world an incidence occurs. So the main focus of ENFSI is to establish common standards for forensic work in Europe.

Therefore, it is hoped that after reading this article, in the future ILAC-members will associate quality issues in forensics science with ENFSI.



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Table 1 – ENFSI Expert Working Groups

1. Digital Imaging
2. DNA
3. Documents
4. Drugs
5. Explosives
6. Textile & Hair
7. Fingerprints
8. Firearms & Gunshot Residues
9. Fire & Explosion Investigation
10. Forensic Information Technology
11. Forensic Speech & Audio Analysis
12. Handwriting
13. Marks
14. Paint & Glass
15. Road Accident Analysis
16. Scene of Crime
17. Animal, Plant and Soil Traces

Membership

ENFSI is a dynamic expanding organization that welcomes new members that meet the ENFSI eligibility criteria. The number of members has rapidly increased over the years from 11 forensic laboratories in 1993 to 63 laboratories from 37 countries today. The number of languages spoken within the ENFSI community is more than 20, which is sometimes a barrier for communication. The chosen working language is English.



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I documenti dell'European Network of Forensic Institutes (ENFSI)

The screenshot shows the ENFSI website interface. The main navigation menu includes Home, About ENFSI, News, Agenda, Projects, and Documents. The breadcrumb trail is: home > about enfsi > structure > working groups > dna. The page title is "DNA" and the sub-section is "Aims and objectives".

ENFSI DNA working group aims and objectives are:

- to bring together organisations actively pursuing forensic DNA analysis purpose of exchanging and disseminating information on forensic applications;
- to discuss, share and compare forensic DNA analytical methods, protocols and research;
- to establish forensic DNA analysis quality assurance guidelines and quality assurance systems in Europe;
- to co-operate with other national and international organisations in developing European standards for forensic DNA analyses;
- to serve as a mechanism for the review and revision of European guidelines for DNA analyses;
- to establish core DNA markers for national and international criminal justice DNA profile databases in Europe;
- to disseminate to the European forensic DNA community ENFSI guidelines, research results, the provision of training and any other work of benefit.

Documents listed:

- ENFSI 2014 Document on DNA-Database Management (Published: 2014-4-28)
- ENFSI survey on DNA databases in Europe (Published: 2014-4-11)
- Recommendations for the training of DNA staff - v2010 (Published: 2012-8-18)
- Minimum validation guidelines in DNA profiling - v2010 (Published: 2012-8-18)
- ENFSI report on DNA Legislation in Europe (Published: 2012-8-18)
- ENFSI Report on Criminal Cases in Europe solved by ILS (Published: 2012-8-18)
- ENFSI DNA WG Terms and Abbreviations (Published: 2012-8-18)
- DNA contamination prevention guidelines for the file contamination prevention final - v2010 (Published: 2012-8-18)



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List of EA Publications and international documents

EA inf /01 rev 25 September 2015

Guidance documents

EA 4/09 G Accreditation for Sensory Testing Laboratories

Eurachem guide Accreditation for microbiological laboratories

EA 4/15 G Accreditation for Non Destructive Testing

EA 4/16 G EA Guidelines on the Expression of Uncertainty in
Quantitative testing

EA 4/14 inf The Selection and Use of Reference Materials





Partecipazione in PT schemes

EA 4/18 INF Guidance on the level and frequency of proficiency testing participation

ILAC P 09 ILAC policy for partecipazione in proficiency test





EA 4/18 INF

CAB shall establish a plan for Quality control.

The plan will include participation in PT schemes.

The participation shall cover the scope of accreditation. To gain this goal the laboratory will identify the subdisciplines





Subdiscipline:

An area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. (e.g. Determination of Arsenic in soil by ICP-MS)





Frequency of participation for subdiscipline

- ❖ The laboratory will establish a PT strategy.
- ❖ This document will be reviewed on annual basis
- ❖ The AB will assess laboratory PT strategy





EA 3/04 G

Use of proficiency test as a tool for accreditation in testing

(Laboratory) proficiency testing

Determination of laboratory testing performance by means of interlaboratory comparisons

Interlaboratory comparisons

Organization, performance and evaluation of test on the same or similar test items by two or more laboratories in accordance with pre-determined conditions.





Bilateral proficiency test(ing)

Laboratory receives a test item with accurately determined characteristics, which are to be tested in the frame of an accreditation procedure. The test item is given either by the assessor or provided by a third party

Blind test item :Sample with undisclosed characteristics to be tested by the laboratory, whose competence in a specific field is to be assessed. This sample is not identified as a sample for proficiency testing





For EA 3/04 proficiency test is one of the tools
to be used in accreditation procedure

Other tools: Bilateral proficiency test

Interlaboratory comparisons designed primarily
for other purpose.





EA 3/04 and accreditation body

- ❖ Accreditation body must have assessors with competence to evaluate PT results
- ❖ AB should judge the appropriateness of proficiency tests in which the laboratory participates
- ❖ AB shall check CAB procedures in participation in PT schemes





ILAC P 9

AB shall have a policy on the use of PT activities in the assessment and accreditation process

AB therefore must establish a procedure containing the following requirements: minimum level and frequency of participation, how participation and performance will be reviewed





ILAC P9

For example AB may request a plan of participation in PT schemes before accreditation and extension are granted

In case of a negative result AB may require an immediate participation to a new PT in order to verify the corrective action taken





Interview during assessment

Esistono procedure di controllo della qualità interno dei materiali e delle attività critiche utilizzati nella esecuzione delle prove?

Sono applicate in modo sistematico in base ad una pianificazione documentata?

Gli esiti della attività di controllo della qualità interno sono rintracciabili dalle registrazioni effettuate?

Viene verificata la ripetibilità?

Esistono procedure di controllo della qualità interno dei materiali e delle attività critiche utilizzati nella esecuzione delle prove?

Sono applicate in modo sistematico in base ad una pianificazione documentata?

Gli esiti della attività di controllo della qualità interno sono rintracciabili dalle registrazioni effettuate?





Highlighted PT

Every year the Working Group ILC Testing of the EA Laboratory Committee selects international PTs and requires to all the Member to ask the accredited laboratories to participate, in some instances without charge.

The highlighted PTs are selected among 3 schemes:

- IMEP (IRMM)
- APLAC
- Professional PT providers (selected from the EPTIS database)

IMEP and APLAC have a limited participation (2-4 laboratories per economy), free of charge





EA highlighted PT

The statistical evaluation is made by the EA-ILC-Testing WG on the basis of the Test Report supplied by the providers.

The results are used to:

- Promote the trust in the Mutual Recognition Agreement
- Enhance technical aspects related to methods or test techniques.
- Enhance the learning points to communicate to assessors and laboratories.





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Alcuni LEARNING POINTS

ILC	Description of the observation	Suggestions
PAH in surface water (WFD)	Some of the laboratories found too low concentrations of PAH compounds of high molecular weight compared with the reference values given.	This was due to the handling of the internal standard. Equilibration times lower than 24 h. In addition the kind and number of the internal standards used did not reflect the properties of the requested PAH compounds. By assessing the analysis of PAH in natural waters and soils special attention should be taken on the handling and composition of the internal standard used.
Heavy metals in toys (EN 71-3:1994)	Taking into account the dispersion of the results and the differences between the results of the reference laboratories the stated uncertainties from the laboratories seem too small. In the test report the application of the correction factor was not always stated, as required.	To be addressed in the audit: In the audit of the method should be focused on the estimation of the measurement uncertainty. Possibly the reported uncertainty is estimated from the measurement only without taking in account the sample preparation step In the test report it must be made clear if the correction factor according to EN 71-3 was applied or not when reporting the results.
All PTs asking for measurement uncertainty	Based on the reported measuring uncertainties it is evident that harmonization in the estimating of uncertainties should be continued. Some of the laboratories didn't report the uncertainty statement. EA labs should make effort to evaluate and report uncertainties.	To be addressed in the audit: Estimation and reporting of measurement uncertainty
Total arsenic, cadmium, copper, lead and mercury, as well as extractable cadmium and lead in mineral feed	- <u>the</u> applied technique seemed to have an influence on the results of all <u>measurands</u> . ICP-MS and HGAAS had the better results - Inappropriate choice of reference material - The analytical methods were not adjusted to the inorganic test material	To be addressed in the audit: - <u>verification</u> of the analytical methods used - <u>reference</u> material should be inorganic as the sample analysed - <u>adjustment</u> on inorganic matrix



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Reference materials

Whenever possible a certified reference material shall be used.

A certified reference material shall be used for validation study and for control of trueness/bias.

For precision study a reference material might be used.





Accredia policy for reference materials and calibration

Whenever possible a certified reference material shall be used. However it's not always possible to find a fit for purpose reference material.

For example in chemistry it's possible to identify three different types of methods:

- 1) methods such as gravimetric methods or volumetric method
- 2) methods using cromatografy or atomic absorption
- 3) methods using X fluorescence or quantometer





Accredia policy for reference materials

1. In the first case equipments must be calibrated by using traceable reference standards
2. In the second case it's not important to use a certified reference material. Reference materials such as solutions with batch number and uncertainty shall be used

In the third case the matrix effect is not negligible. A certified reference material similar to the matrix shall be used.





ACCREDIA REQUIREMENTS: expiring date of critical reagents

The laboratory must handle the expiring dates of critical reagents and reference materials, defining it when not available from manufacturer.

In this view it is to be noted that each laboratory must have rules to establish the expiring date, once opened the packing of reference materials and reagents: during the assessment the technical assessor will take care to judge the rightness of criteria. In addition in view of the rivalidation of solutions once expired, it could be usefull the use of control charts, which could be an help to ascertain if the properties remain steady and within the uncertainty accepted by the client.





Eurachem Guide AML 2013.P2

The Guide provides useful information for application of ISO/IEC 17025 in a microbiology laboratory.

For example the guide gives suggestions for frequency in calibration and maintenance of equipments.





Assessment of a microbiological laboratory

The AB shall assess the laboratory calibration policy (e.g. calibration plan, procedures, records)
If the laboratory has established rules not consistent with Eurachem guide (e.g. a longer period for calibration of Reference thermocouples), the AB shall verify calibration data supporting the laboratory choice.

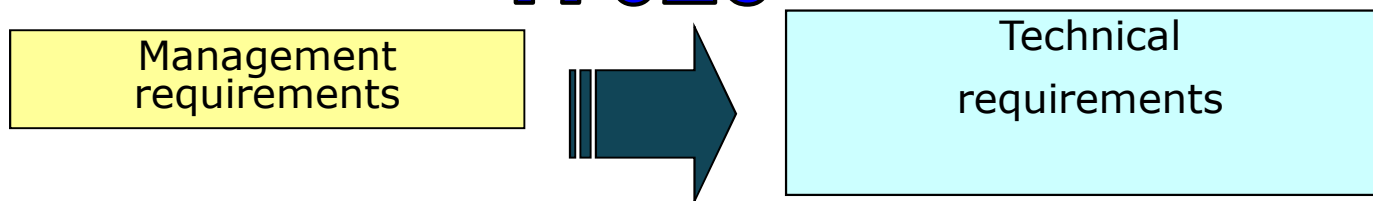
For example the AB shall check control chart of calibration data
On a long period.



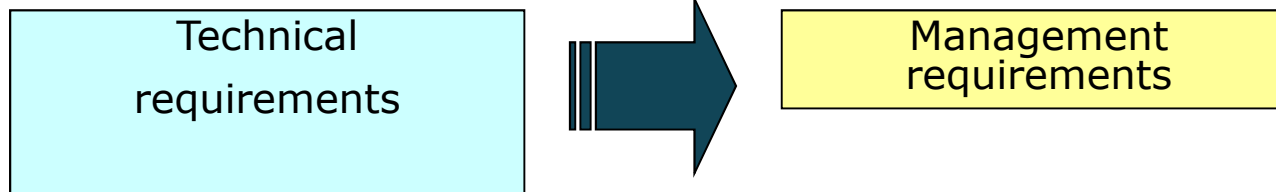


ISO IEC 17043

17025



17043





Management requirements

- 5.1 Organization
- 5.2 Management system
- 5.3 Document control
- 5.4 Review of requests, tenders and contracts
- 5.5 Subcontracting services
- 5.6 Purchasing services and supplies
- 5.7 Service to the customer
- 5.8 Complaints and appeals
- 5.9 Control of nonconforming work
- 5.10 Improvement
- 5.11 Corrective actions
- 5.12 Preventive actions
- 5.13 Control of records
- 5.14 Internal audits
- 5.15 Management reviews





Organization ISO 17043 versus ISO 17025

ISO 17043 is more focused on impartiality (5.1.4) and technical competence of personell 5.1.5 f, I

5.1.4: If the proficiency testing provider is part of an organization performing other activities, then the proficiency testing provider shall identify the responsibilities of key personnel in the organization that have an involvement in or could have influence on the proficiency test activities, in order to identify potential conflicts of interest. Where potential conflicts of interest are identified, procedures shall be put in place to ensure that all activities of the proficiency testing provider are conducted with impartiality.





Subcontracting services

ISO 17025 doesn't establish particular rules

ISO 17043 doesn't allow subcontracting for every activity.

The proficiency testing provider shall not subcontract the planning of the proficiency test scheme the evaluation of performance or the authorization of the final report .





ACCREDIA requirements RT-27

- Subcontractor shall be competent for the task to be carried out
- The PT Provider is responsible for the evaluation of the competence of the subcontractor.
- Accreditation ISO/IEC 17025 of the subcontractor is an adequate condition to establish competence





5.8 Complaints and appeals

Appeals not present in ISO IEC 17025





5.13.2 Technical records

- a) results of homogeneity and stability testing;
- b) instructions to participants;
- c) participants' original responses;
- d) collated data for statistical analysis;
- e) information required for reports (see 4.8); and
- f) final reports (summary or individual, or both).





4 Technical Requirements

4.2 Personnel

4.3 Equipment, accommodation and environment

4.4 Design of proficiency testing schemes

4.5 Choice of method or procedure.....

4.6 Operation of proficiency testing schemes

4.7 Data analysis and evaluation of proficiency testing scheme results

4.8 Reports

4.9 Communication with participants

4.10 Confidentiality.





Personell

The organization must establish the adequate level of experience and qualification.

Personell shall be formally authorized





Design of proficiency test scheme

The proficiency testing provider shall not subcontract the planning of the proficiency testing scheme.

A plan shall be documented before starting the scheme





Information required

- a) the name and address of the proficiency testing provider;
- b) the name, address and affiliation of the coordinator and other personnel involved in the design and operation of the proficiency testing scheme;
- c) the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the proficiency testing scheme;
- d) criteria to be met for participation;
- e) the number and type of expected participants in the proficiency testing scheme;
- f) selection of the measurand(s) or characteristic(s) of interest, including information on what the participants are to identify, measure, or test for in the specific proficiency testing round;
- g) the potential major sources of errors involved in the area of proficiency testing offered;
- i) requirements for the production, quality control, storage and distribution of proficiency test items;





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- j) reasonable precautions to prevent collusion between participants or falsification of results, and procedures to be employed if collusion or falsification of results is suspected;
- k) a description of the information which is to be supplied to participants and the time schedule for the various phases of the proficiency testing scheme;
- l) for continuous proficiency testing schemes, the frequency or dates upon which proficiency test items are to be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which testing or measurement is to be carried out by participants;
- m) any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements;
- n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of proficiency test items and, where applicable, to determine their biological viability;



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- o) preparation of any standardized reporting formats to be used by participants;
- p) a detailed description of the statistical analysis to be used;
- q) the origin, metrological traceability and measurement uncertainty of any assigned values;
- r) criteria for the evaluation of performance of participants;
- s) a description of the data, interim reports or information to be returned to participants;
- t) a description of the extent to which participant results, and the conclusions that will be based on the outcome of the proficiency testing scheme, are to be made public; and
- u) actions to be taken in the case of lost or damaged proficiency test items.





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How can the organization deals with this kind of information?

This information can be available on the web site



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Preparation of proficiency test item Homogeneity and stability

The organization must establish procedures to assess homogeneity and stability in order to ensure that every participant receives comparable proficiency test items, and that these proficiency test items remain stable throughout the proficiency testing. These activities (test item preparation, homogeneity and stability) can be subcontracted or handled by the organization itself.





The importance of homogeneity and stability

Usually PT Provider subcontract sample preparation and homogeneity and stability. The PT provider shall have criteria to subcontract these activities and shall maintain records of subcontractor evaluation.





Homogeneity and stability

If a particular scheme regards the measurement of different analytes, the homogeneity study must be carried out for each analyte or for any “analyte target”.

Example of finding during an assessment:

The evaluation of homogeneity has been carried out with analytical methods not specific for each molecule but for their amount.





The assessment of homogeneity shall normally be performed after the proficiency test items have been packaged in the final form and before distribution to participants unless it's not possible to wait for the nature of the matrix.

Example of finding during an assessment:

Due to the nature of the matrix (waste water) the sample has been sent to the participants before the evaluation of the homogeneity. The participant has not been informed.





Statistical design and establishing the assigned values

The proficiency testing provider shall document the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results, and shall provide a description of the reasons for their selection and assumptions upon which they are based. The proficiency testing provider shall be able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures. Besides the PT Provider shall establish the minimum number of participants in the proficiency testing scheme needed to meet the objectives of the statistical design.





Statistical design

Example of findings during assessment:

The PT Provider has established in 10 the number of participants for the consistency of the statistical method.

The PT has not established a procedure to inform the participant when the number of participants is less than 10.





Instructions for participants

The proficiency testing provider shall give detailed documented instructions to all participants.

Instructions to participants shall include:

- a) the necessity to treat proficiency test items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the proficiency testing scheme which require departure from this principle);
- b) details of factors which could influence the testing or calibration of the proficiency test items, e.g. the nature of the proficiency test items, conditions of storage, whether the proficiency testing scheme is limited to selected test methods, and the timing of the testing or measurement;
- c) detailed procedure for preparing or conditioning, or both preparing and conditioning, of the proficiency test items before conducting the tests or calibrations;





- d) any appropriate instructions on handling the proficiency test items, including any safety requirements;
- e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement;
- f) specific and detailed instructions on the manner of recording and reporting test or measurement results and associated uncertainties. If the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability;





Packaging, labelling and distribution of proficiency test items

The proficiency testing provider shall control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements.

The proficiency testing provider shall follow a procedure to enable the confirmation of delivery of the proficiency test items.





Data analysis and evaluation of proficiency testing scheme results

Results received from participants shall be recorded and analysed by appropriate methods.

Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.

All data processing equipment and software shall be validated in accordance with procedures before being brought into use. Computer system maintenance shall include a back-up process and system recovery plan. The results of such maintenance and operational checks shall be recorded.





Reports

Reports shall include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

- a) the name and contact details for the proficiency testing provider;
- b) the name and contact details for the coordinator;
- c) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the report;
- d) an indication of which activities are subcontracted by the proficiency testing provider;
- e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
- f) page numbers and a clear indication of the end of the report;
- g) a statement of the extent to which results are confidential;
- h) the report number and clear identification of the proficiency testing scheme;
- i) a clear description of the proficiency test items used, including necessary details of the proficiency test item's preparation and homogeneity and stability assessment;





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- j) the participants' results;
- k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
- l) procedures used to establish any assigned value;
- m) details of the metrological traceability and measurement uncertainty of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;
- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);
- p) comments on participants' performance by the proficiency testing provider and technical advisers;
- q) information about the design and implementation of the proficiency testing scheme;
- r) procedures used to statistically analyse the data;
- s) advice on the interpretation of the statistical analysis; and
- t) comments or recommendations, based on the outcomes of the proficiency testing round



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Communication with participants

Fees for participation

How to apply

Any relevant detail concerning the scope of the scheme

Participants shall be advised for any change

Participants shall receive information concerning appeals





Confidentiality

The identity of participants in a proficiency testing scheme shall be confidential and known only to persons involved in the operation of the proficiency testing scheme, unless the participant waives confidentiality.

When an interested party requires the proficiency testing results to be directly provided by the proficiency testing provider, the participants shall be made aware of the arrangement in advance of participation.

In exceptional circumstances, when a regulatory authority requires proficiency testing results to be directly provided to the authority by the proficiency testing provider, the affected participants shall be notified of this action in writing.





Statistical methods

When assessing a PT provider it's necessary that one of the team members is competent for ISO 13528 or IUPAC PROTOCOL





ILAC P10

Equipment and reference standards shall be calibrated by

1. An NMI whose service is suitable for the intended need and is covered by the CIPM MRA.
2. An accredited calibration laboratory whose service is suitable for the intended need and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.





ILAC P10

when 1) or 2) are not possible for a particular calibration:

3a. An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.

3b. A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.





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ILAC P10

AB shall establish a policy regarding traceability



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ACCREDIA POLICY

All calibrations must be traceable to primary samples produced by Metrological Institutions and performed by CABs' accredited for the specific measure by AB mutually recognized by EA or ILAC. If the laboratory executes calibration by himself, he must have available traceable first line reference standards.

This paragraph is applicable to laboratories that perform in house calibrations. In such cases the laboratories shall hold the required reference standards and operate with appropriate documented technical procedures.





Accredia Laboratory Department and EA 2/13

- ✓ Request from foreign AB
- ✓ Request of information or documents in order to verify that EA 2/13 conditions apply
- ✓ Agreement between FAB and ACCREDIA.
- ✓ Appointment of auditors
- ✓ Assessment according ISO /IEC 17025 and EA and ILAC documents(ACCREDIA requirements will not apply)
- ✓ Reports and findings in English will be sent to FAB





Accredia Laboratory Department and EA 2/13

For multisite accreditation the following conditions shall be met and apply irrespective of the legal personality of the local sites:

The accreditation certificate issued by the National Accreditation Body, of the country where the head office is established shall name one legal entity, that of the head office, and it shall be this legal entity that holds the multisite accreditation and is responsible for the accredited activities of the conformity assessment body, including any activity performed by the local sites that forms part of the scope of accreditation.





Accredia Laboratory Department and EA 2/13

The head office and all of the sites to be included under the accreditation shall operate under the same management and the same global quality management system.

The head office shall have the means to substantially influence and control the activities of the sites. The head office shall be able to demonstrate that such influence and control is in place and properly working

Where these local sites carry out key activities as defined in EN ISO/IEC 17011 (see also IAF/ILAC A5), then the accreditation certificate shall in its annexes clearly identify the address of these sites.

Key activities : policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review etc..

