ELSEVIER

Forensic Science International 129 (2002) 148–157

Forensic Science International

www.elsevier.com/locate/forsciint

Paternity Testing Commission of the International Society of Forensic Genetics: recommendations on genetic investigations in paternity cases

Niels Morling[a,*], Robert W. Allen[b], Angel Carracedo[c], Helena Geada[d], Francois Guidet[e], Charlotte Hallenberg[a], Wolfgang Martin[f], Wolfgang R. Mayr[g], Bjørnar Olaisen[h], Vince L. Pascali[i], Peter M. Schneider[j]

[a]*Department of Forensic Genetics, Institute of Forensic Medicine, University of Copenhagen, 11 Frederik V's Vej, DK-2100 Copenhagen Ø, Denmark*

[b]*Chapman Institute, Schusterman HSC, 44503 East 41 Street, Tulsa, OK 74135, USA*

[c]*Institute of Legal Medicine, University of Santiago de Compostela, E-15705 Santiago de Compostela, Spain*

[d]*Gabinete de Medicina Legal, Instituto de Medicina Legal de Lisboa, Rua Manuel Bento de Sousa, 1150-219 Lisboa, Portugal*

[e]*Laboratoire de Genetique Moleculaire, Institut de Biologie, CHU-Hotel Dieu, 9 Quai Moncousu, F-44093 Nantes Cedex 1, France*

[f]*Institut für Blutgruppenserologie und Genetik, Holsteinischer Kamp 67, D-22081 Hamburg, Germany*

[g]*University Clinic for Blood Group Serology and Transfusion Medicine, University of Vienna, A-1090 Vienna, Austria*

[h]*Rettsmedisinsk Institut, University of Oslo, Rikshospitalet, N-0027 Oslo, Norway*

[i]*Istituto Medicina Legale, Universita Católica, Largo Francesco Vito 1, I-00168 Rome, Italy*

[j]*Institut für Rechtsmedizin, Universität Mainz, Am Pulverturm 3, D-55131 Mainz, Germany*

Received 15 July 2002; accepted 15 July 2002

Abstract

The International Society for Forensic Genetics (ISFG) has established a Paternity Testing Commission (PTC) with the purpose of formulating international recommendations concerning genetic investigations in paternity testing. The PTC recommends that paternity testing be performed in accordance with the ISO 17025 standards. The ISO 17025 standards are general standards for testing laboratories and the PTC offers explanations and recommendations concerning selected areas of special importance to paternity testing.

Keywords: International Society for Forensic Genetics (ISFG); Paternity Testing Commission (PTC); DNA investigations; Recommendation; ISO 17025 standard

1. Introduction

Paternity testing has undergone great changes during the last 10–15 years with the implementation of DNA investigations in almost all countries. DNA investigations have a very great informative potential in paternity testing if the investigations are performed and interpreted correctly.

With the general availability of genetic testing, the need for international recommendations becomes more and more obvious. In 1982, a conference on parentage testing was held in Arlington with the participation of scientists from the US and seven European countries. The work resulted in a very comprehensive book with comments to a number of problems relating to paternity testing including a summary of conclusions and guidelines of the conference [1].

Most recommendations and standards on paternity testing are formulated by local organisations, e.g. the Standards for Parentage Testing Laboratories (5th Edition) of the American Association of Blood Banks (AABB) [2].

* Corresponding author. Tel.: +45-35-32-61-10; fax: +45-35-32-61-20.
E-mail address: niels.morling@forensic.ku.dk (N. Morling).

0379-0738/02/$ – see front matter
PII: S0379-0738(02)00289-X

The European Federation for Immunogenetics (EFI) has included paternity testing standards in Standards for Histocompatibility Testing [3].

The DNA Commission of the International Society for Forensic Genetics (ISFG) has published a number of recommendations on the use of DNA-based typing in forensic genetics [4–16], but none of the recommendations are focusing on paternity testing. The recommendations are either broad or with special reference to forensic casework.

The board of the ISFG found that it would be important and helpful to scientists if international recommendations for paternity testing could be established.

2. Establishing the Paternity Testing Commission

The board of the ISFG decided to establish a Paternity Testing Commission (PTC) with members from the English, French, German, Italian, Japanese, Spanish/Portuguese speaking working groups, the American Association of Blood Banks as well as the ISFG board members in order to get a broad representation in the commission. The working groups appointed the representatives of the working groups.

3. Work of the commission

The members of the Paternity Testing Commission are listed in Annex 1. The commission began the work in January 2001 and has held four meetings. A significant part of the work was done by circulating suggestions and comments through email. The work was financed by the ISFG.

4. General considerations of the PTC

The members of the commission reported on the current situation of paternity testing in the countries that they represent and summarised the issues they would like to be addressed. Variations in procedures due to differences in laws and traditions as well as similarities in procedures were identified.

At an early point, the commission realised that it would not be possible to consider all interests and that—if agreement should be obtained—the only possible way forward was to formulate basic recommendations for paternity testing laboratories. These may serve as a platform to develop more detailed local standards addressing the specific technical and legal requirements in a country. Such standards can be made locally as demonstrated e.g. by the AABB [2].

The quality of paternity testing depends on a number of issues including management of laboratory, personnel, quality systems, technical performance, and reporting. The members agreed that it is important that paternity testing is performed according to laboratory quality standards. The PTC decided to recommend the international laboratory standard concerning measurement and testing, the ISO 17025: 1999 standard ‘General requirements for the competence of testing and calibration laboratories’ [17] for paternity testing laboratory investigations.

The requirements in ISO 17025 are stated in general terms. ISO anticipated that explanations (also called applications in the ISO language) may be needed for a specific area—see Annex B of ‘Guidelines for establishing applications for specific fields, ISO 17025: 1999’. It should be emphasised that explanations (applications) can not include additional general requirements not covered by ISO 17025. It is also important to understand that—if one accept the ISO 17025 standard—it is not possible to change any paragraph of the standards.

The commission decided to identify areas in the ISO 17025 standards that need explanation and add the explanations related to paternity testing to the ISO 17025 document as suggested in Annex B of ISO 17025: 1999.

The PTC members discussed each paragraph of ISO 17025 and found that ISO 17025—with very few additional explanations—would reflect what the commission considers basic standards for paternity testing. The commission decided to use the word recommendation for the explanations in accordance with the wording of previous publications of recommendations of the ISFG. The recommendations clarify the standards with special reference to paternity testing, and the recommendations do not change any ISO paragraph.

5. Comments to some of the specific ISFG-recommendations

In case of doubt of the results or interpretation, it is important to have the possibility of a confirmatory test and a second opinion (see 4.8).

The same requirements of qualifications are recommended for laboratory directors and for scientists who are authorised for signing reports because the report is the final, crucial product of the investigations. The commission is aware of the possible need for more specific requirements in some countries. However, the conditions and the needs differ from country to country and the specifications of qualifications must be defined and implemented locally (5.1 and 5.2).

The common use of PCR-based techniques makes it necessary to stress the importance of precautions against contamination with PCR products (5.3.3., 5.3.5 and 5.5.1).

Genetic testing methods and method validation are key points in paternity testing—as in all testing. The commission identified a number of important items that are specific to paternity testing. However, the majority of the items are handled differently in each country according to local law and agreements. Thus, the choice of methods and genetic systems should be based on an agreement between the client(s) and the laboratory clearly specifying the quality of the testing (see 5.4).

Almost all aspects of reporting of paternity testing results are covered by ISO 17025. The evaluation of the weight of

the evidence of the results is influenced by local traditions and national law and thus varies to a high degree among countries. However, the PTC finds that the weight of the evidence of paternity testing results shall be presented in an objective way by means of commonly agreed statistical methods based on the likelihood ratio principle (5.10).

6. A short guide to ISO 17025

The ISO 17025: 1999 standard 'General requirements for the competence of testing and calibration laboratories' [17] can be purchased in paper and electronic versions either from the International Organisations for Standardisation or the National Bureau of Standardisation.

The ISO 17025 standard supersedes the European Norm EN 45001: 1989, and it cancels and replaces ISO Guide 25: 1990. The ISO 17025 standard exist in three official versions—English, French and German. Official translations of the ISO 17025 document exist into all languages of states belonging to the CEN/CENELEC. Member states are bound to comply with the standard.

ISO 17025 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

Laboratories conforming to the ISO 17025 standard will also conform to the standards of the ISO 9000 series. Certification against ISO 9001 and ISO 9002 does not by itself demonstrate the competence of the laboratory to produce technically valid data and results (refer ISO 17025 'Introduction').

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO 17025. Thus, safety issues are regulated locally.

The reader is referred to the text of ISO 17025 for further details of the standards.

7. How to read the ISFG-recommendations

Below is a short extract of the main statements of DS/EN ISO/IEC 17025 with the permission of Dansk Akkreditering together with the ISFG-recommendations. The comments of the PTC are in italic. The text is in no way complete and the short extract of ISO 17025 cannot be used alone. The reader is referred to the full text of the ISO 17025 document.

The part concerning reporting the results is more detailed than the rest because the report is the essence of paternity testing.

8. ISFG-recommendations on paternity testing

The Paternity Testing Commission of the International Society for Forensic Genetics recommends that genetic testing, including sampling be performed according to the ISO 17025 standards.

The Paternity Testing Commission of the International Society for Forensic Genetics offers the following explanations or recommendations to the paragraphs of ISO 17025.

8.1. Recommendations specific to paternity testing according to ISO 17025 paragraphs

1 Scope

Main statement: The ISO 17025 standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. *Accepted without comments*.

2 Normative references

The paragraph refers to a number of normative documents. *Accepted without comments*.

3 Terms and definitions

The paragraph clarifies details concerning terms and definitions. *Accepted without comments*.

4 Management requirements

The paragraph specifies a number of basic management requirements. The commission feels that the standards are very useful to all paternity testing laboratories.

4.1 Organisation

Main statement: The laboratory shall carry out its testing activities in such a way as to meet the requirements of ISO 17025 and to satisfy the needs of the client, the regulatory authorities or organisations providing recognition. *Accepted without comments*.

4.2 Quality system

Main statement: The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. *Accepted without comments*.

4.3 Document control

Main statement: The laboratory shall establish and maintain procedures to control all documents that form part of its quality system. *Accepted without comments*.

4.4 Review of requests, tenders and contracts

Main statement: The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. *Accepted without comments*.

4.5 Subcontracting of tests and calibrations

Main statement: When a laboratory subcontracts work, this work shall be placed with a competent subcontractor. *Accepted without comments*.

4.6 Purchasing services and supplies

Main statement: The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests. *Accepted without comments*.

4.7 Service to the client

Main statement: The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

When the amount of sample material is sufficient, the laboratory shall perform testing in such a way that it is possible for another laboratory to perform a confirmatory test.

4.8 Complaints

Main statement: The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

In case of complaints, the laboratory shall inform the client of the possibility of obtaining a second opinion from another laboratory.

4.9 Control of nonconforming testing and/or calibration work

Main statement: The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. *Accepted without comments*.

4.10 Corrective action

Main statement: The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified. *Accepted without comments*.

4.11 Preventive action

Main statement: Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement. *Accepted without comments*.

4.12 Control of records

Main statement: The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. *Accepted without comments*.

4.13 Internal audits

Main statement: The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and ISO 17025. *Accepted without comments.*

4.14 Management reviews

Main statement: In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. *Accepted without comments*.

5 Technical requirements

The paragraph specifies general requirements for laboratories performing testing. The commission feels that the standards are very useful to all paternity testing laboratories.

5.1 General

Main statement: The laboratory shall take account of factors that determine the correctness and reliability of the tests performed by a laboratory. *Accepted without comments.*

5.2 Personnel

Main statement: The laboratory management shall ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. *Accepted with the addition of the following recommendations*:

ISFG-recommendation 1

Requirements to a laboratory director:

- Education at the university level comparable to a Master's degree in human genetics from a UK university or other relevant education (5–6 years of study).
- At least 3 years of training in a competent paternity testing laboratory according to the ISFG-recommendations under the supervision of a competent supervisor according to the ISFG-recommendations.
- Experience shall be documented by preparation of at least 100 reports covering all major aspects of paternity testing.

ISFG-recommendation 2

Requirements to a scientist who is authorised to sign reports:

- The same requirements apply to a scientist authorised to sign reports as to a laboratory director.

5.3 Accommodation and environmental conditions

5.3.1 *Main statement:* Laboratory facilities for testing, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests. *Accepted without comments*.

5.3.2 *Main statement:* The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. *Accepted without comments*.

5.3.3 *Main statement:* There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

A laboratory performing testing with the use of PCR shall take the necessary steps to prevent contamination with PCR products by dividing the laboratory into the following work areas:

- Separate work areas for work that does not require special attention concerning contamination from PCR products.
- Separate work areas for PCR set-up with special attention to avoid contamination of the samples.
- Separate work areas for handling of PCR products with special attention to avoid contamination from these areas to other areas in the laboratory.

5.3.4 *Main statement:* Access to and use of areas affecting the quality of the tests shall be controlled. *Accepted without comments*.

5.3.5 *Main statement:* Measures shall be taken to ensure good house keeping in the laboratory. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

A laboratory performing PCR-based testing shall have procedures to monitor potential contamination with PCR products.

5.4 Test and calibration methods and method validation

5.4.1 General

Main statement: The laboratory shall use appropriate methods and procedures for all tests within its scope, including sampling, handling, transport, storage and preparation of items to be tested and, where appropriate, an estimation of the measurement uncertainty, as well as statistical techniques for analysis of test data. *Accepted without comments*.

5.4.2 Selection of methods

Main statement: The laboratory shall use test methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests it undertakes. *Accepted with the addition of the following recommendations*:

ISFG-recommendation 1

A laboratory performing paternity testing shall use systems for which proficiency testing is available.

ISFG-recommendation 2

- Population distribution data for the systems used shall be documented and used appropriately.
- Mutation frequencies of the systems used shall be documented and used appropriately.

5.4.3 Laboratory-developed methods

Main statement: Introduction of test methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. *Accepted without comments*.

5.4.4 Non-standard methods

Main statement: When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test. The method developed shall have been validated appropriately before use. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

- Non-standard methods shall not be used as the only method(s) for paternity testing.
- Non-standard methods shall be used only if it can be documented that the method is used in at least one other laboratory thus making it possible to obtain a second opinion based on repeated testing.

5.4.5 Validation of methods

5.4.5.1 *Main statement:* Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. *Accepted without comments*.

5.4.5.2 *Main statement:* The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. *Accepted with the alteration of the following*:

ISFG-recommendation

'NOTE 2: The techniques used for the determination of the performance of a method shall be *all* of the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- inter-laboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.'

5.4.5.3 *Main statement:* The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), assessed for the intended use, shall be relevant to the clients' needs. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

The laboratory shall use relevant population frequency data (databases) for ethnic groups that are referred to in routine work. If a database from another laboratory is used for comparisons, it shall be documented that the database used is relevant for the purpose and that the results in the database were obtained with methods that give results that are comparable to those used for the case work.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 *Main statement:* A testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations. *Accepted without comments*.

5.4.6.2 *Main statement:* Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

The measurement uncertainty of tests shall be known and shall be included in the interpretation of the results.

5.4.6.3 *Main statement:* When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis. *Accepted without comments*.

5.4.7 Control of data

5.4.7.1 *Main statement:* Calculations and data transfers shall be subject to appropriate checks in a systematic manner. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

All manual calculations shall be performed in duplicate and shall be reviewed by an authorised scientist or laboratory director.

5.4.7.2 *Main statement:* When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that user-developed computer software is documented and validated, and that procedures are established and implemented for protecting the data. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

All computer-assisted calculations shall be validated and reviewed by an authorised scientist or the laboratory director before serving as the basis for a final report.

5.5 Equipment

5.5.1 *Main statement:* The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

When performing analysis with the use of PCR, dedicated equipment shall be used for pre-PCR and post-PCR processes, respectively.

5.5.2 *Main statement:* Equipment and its software used for testing and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned. *Accepted without comments*.

5.5.3 *Main statement:* Equipment shall be operated by authorised personnel. Up-to-date instructions on the use and maintenance of equipment shall be readily available. *Accepted without comments*.

5.5.4 *Main statement:* Each item of equipment and its software used for testing and significant to the result shall, when practicable, be uniquely identified. *Accepted without comments*.

5.5.5 *Main statement:* Records shall be maintained of each item of equipment and its software significant to the tests performed. *Accepted without comments*.

5.5.6 *Main statement:* The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration. *Accepted without comments*.

5.5.7 *Main statement:* Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. *Accepted without comments*.

5.5.8 *Main statement:* Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due. *Accepted without comments*.

5.5.9 *Main statement:* When, for whatever reason, equipment goes out side the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. *Accepted without comments*.

5.5.10 *Main statement:* When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure. *Accepted without comments*.

5.5.11 *Main statement:* Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated. *Accepted without comments*.

5.5.12 *Main statement:* Test and calibration equipment, including both hardware and software, shall be safeguarded

from adjustments which would invalidate the test and/or calibration results. *Accepted without comments*.

5.6 Measurement traceability

5.6.1 General

Main statement: All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. *Accepted without comments*.

5.6.2.1.1 *Main statement:* For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités). *Accepted without comments*.

5.6.2.1.2 *Main statement:* There are certain calibrations that currently cannot be strictly made in SI units. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards. Participation in a suitable programme of interlaboratory comparisons is required where possible. *Accepted without comments*.

5.6.2.2 Testing

5.6.2.2.1 *Main statement:* For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. *Accepted without comments*.

5.6.2.2.2 *Main statement:* Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2). *Accepted without comments*.

5.6.3.1 Reference standards

Main statement: The laboratory shall have a programme and procedure for the calibration of its reference standards that provide traceability. *Accepted without comments*.

5.6.3.2 Reference materials

Main statement: Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable. *Accepted without comments*.

5.6.3.3 Intermediate checks

Main statement: Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules. *Accepted without comments*.

5.6.3.4 Transport and storage

Main statement: The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity. *Accepted without comments*.

5.7 Sampling

5.7.1 *Main statement:* The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

Procedures guaranteeing the identity of the individual from which the sample is taken and the traceability of the sample shall be covered by the contract with the clients.

5.7.2 *Main statement:* Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test results, and shall be communicated to the appropriate personnel. *Accepted without comments*.

5.7.3 *Main statement:* The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing that is undertaken. *Accepted without comments*.

5.8 Handling of test and calibration items

5.8.1 *Main statement:* The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

If test items (samples) are used for other purposes such as reference material, scientific purposes, etc. this shall be covered by the contract with the clients.

5.8.2 *Main statement:* The laboratory shall have a system for identifying test items. *Accepted without comments*.

5.8.3 *Main statement:* Upon receipt of the test item, abnormalities or departures from normal or specified conditions, as described in the test method, shall be recorded. *Accepted without comments*.

5.8.4 *Main statement:* The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test item during storage, handling and preparation. *Accepted without comments*.

5.9 Assuring the quality of test and calibration results

Main statement: The laboratory shall have quality control procedures for monitoring the validity of tests undertaken. *Accepted with the addition of the following recommendation*:

ISFG-recommendation

The laboratory shall participate in proficiency testing programmes at least two times a year and the results shall be graded.

5.10 Reporting the results

5.10.1 General

Main statement: The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, usually in a test report, and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.10.2–5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations. *Accepted without comments*.

5.10.2 Test reports and calibration certificates

Main statement: Each test report shall include at least the following information, unless the laboratory has valid reasons for not doing so:

(a) a title (e.g. ''Test Report'');
(b) the name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory;
(c) unique identification of the test report (such as the serial number), and on each page an identification in order to ensure that the page is recognised as a part of the test report, and a clear identification of the end of the test report;
(d) the name and address of the client;
(e) identification of the method used;
(f) a description of, the condition of, and unambiguous identification of the item(s) tested;
(g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test;
(h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
(i) the test results with, where appropriate, the units of measurement;
(j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorising the test report;
(k) where relevant, a statement to the effect that the results relate only to the items tested.

Accepted with the addition of the following recommendation:

ISFG-recommendation:

If the weight of the evidence is calculated, it shall be based on likelihood ratio principles. The Paternity Index (PI) is a likelihood ratio:

$$\mathrm{PI} = \frac{\text{probability (types observed}\,|\,\text{the hypothesis is that the tested man is the father)}}{\text{probability (types observed}\,|\,\text{the hypothesis is that a random man is the father)}}.$$

If other values based on likelihood ratio principles are presented, e.g. Wahrscheinlichkeit *W*, the premises and assumptions for the calculations shall be clearly specified.

5.10.3 Test reports

5.10.3.1 *Main statement:* In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

(a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
(b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
(c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instructions or requires, or when the uncertainty affects compliance to a specification limit;
(d) where appropriate and needed, opinions and interpretations (see 5.10.5);
(e) additional information which may be required by specific methods, clients or groups of clients.

Accepted without comments.

5.10.3.2 *Main statement:* In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

(a) the date of sampling;
(b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

(c) the location of sampling, including any diagrams, sketches or photographs;
(d) a reference to the sampling plan and procedures used;
(e) details of any environmental conditions during sampling that may affect the interpretation of the test results;
(f) any standard or other specification for the sampling method or procedure, and eviations, additions to or exclusions from the specification concerned.

Accepted without comments.

5.10.4 Calibration certificates

This section relates to calibration certificates not relevant to paternity testing.

5.10.5 Opinions and interpretations

Main statement: When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report. *Accepted without comments*.

5.10.6 Testing and calibration results obtained from subcontractors

Main statement: When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically. *Accepted without comments*.

5.10.7 Electronic transmission of results

Main statement: In the case of transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of ISO 17025 shall be met. *Accepted without comments*.

5.10.8 Format of reports and certificates

Main statement: The format shall be designed to accommodate each type of test carried out and to minimise the possibility of misunderstanding or misuse. *Accepted without comments*.

5.10.9 Amendments to test reports and calibration certificates

Main statement: Material amendments to a test report after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

''Supplement to Test Report, serial number ... [or as otherwise identified]'', or an equivalent form of wording. Such amendments shall meet all the requirements of ISO 17025.

When it is necessary to issue a complete new test report, this shall be uniquely identified and shall contain a reference to the original that it replaces. *Accepted without comments*.

Annex 1: Members of the Paternity Testing Commission

Dr. Robert W. Allen, Chapman Institute, Tulsa Oklahoma, USA;
Prof. Angel Carracedo, Institute of Legal Medicine, Santiago de Compostela, Spain;
Dr. Helena Geada, Institute of Legal Medicin, Lisbon, Portugal;
Dr. Francois Guidet, Laboratory of Molecular Genetics, Nantes, France;
Dr. Charlotte Hallenberg, Department of Forensic Genetics, Institute of Forensic Medicine, University of Copenhagen, Denmark;
Dr. Wolfgang Martin, Institute of Blood Group Serology and Genetics, Hamburg, Germany;
Prof. Wolfgang R. Mayr, University Clinic for Blood Group Serology and Transfusion Medicine, University of Vienna, Austria;
Dr. Niels Morling, Department of Forensic Genetics, Institute of Forensic Medicine, University of Copenhagen, Denmark;
Prof. Dr. med. Björnar Olaisen, Lovund, Norway;
Prof. Vince Pascali, Institute of Legal Medicine, The Catholic University, Rome, Italy;
Prof. Peter M. Schneider, Institute of Legal Medicine, University of Mainz, Germany.

References

[1] R.H. Walker (Ed.), Inclusion Probabilities in Parentage Testing, American Association of Blood Banks, Arlington, Virginia, USA, 1983.
[2] Standards for Parentage Testing Laboratories, 5th ed., American Association of Blood Banks, Bethesda, Maryland, USA, 2001.
[3] The Paternity Testing Standards Included in Standards for Histocompatibility Testing, version 4, European Federation for Immunogenetics (EFI), 2000, http://www.efiweb.org/standards_pt14.htm.
[4] Recommendations of the Society for Forensic Haemogenetics concerning DNA polymorphisms, Forensic Sci. Int. 43 (1989) 109–111 (editorial).
[5] Second DNA recommendations: 1991 report concerning recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of DNA polymorphisms, Forensic Sci. Int. 52 (1992) 125–130 (editorial).
[6] Second DNA recommendations: 1991 report concerning recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of DNA polymorphisms, Int. J. Legal Med. 104 (1992) 361–364 (editorial).
[7] Second DNA recommendations: 1991 report concerning recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of DNA polymorphisms, Vox Sang. 63 (1992) 70–73 (editorial).
[8] Recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of PCR-based polymorphisms, Forensic Sci. Int. 55 (1992) 1–3 (editorial).

[9] Recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of PCR-based polymorphisms, Int. J. Legal Med. 105 (1992) 63–64 (editorial).

[10] Recommendations of the DNA Commission of the International Society for Forensic Haemogenetics relating to the use of PCR-based polymorphisms, Vox Sang. 64 (1993) 124–126 (editorial).

[11] Statement by DNA Commission of the International Society for Forensic Haemogenetics concerning the National Academy of Sciences report on DNA Technology in Forensic Science in the USA, Forensic Sci. Int. 59 (1993) 1–2 (editorial).

[12] W. Bär, B. Brinkmann, B. Budowle, A. Carracedo, P. Gill, P. Lincoln, W. Mayr, B. Olaisen, DNA recommendations: further report of the DNA Commission of the ISFH regarding the use of short tandem repeat systems, Forensic Sci. Int. 87 (1997) 181–184.

[13] W. Bär, B. Brinkmann, B. Budowle, A. Carracedo, P. Gill, P. Lincoln, W. Mayr, B. Olaisen, DNA recommendations: further report of the DNA Commission of the ISFH regarding the use of short tandem repeat systems, Int. J. Legal Med. 110 (1997) 175–176.

[14] W. Bär, B. Brinkmann, B. Budowle, A. Carracedo, P. Gill, P. Lincoln, W. Mayr, B. Olaisen, DNA recommendations: further report of the DNA Commission of the ISFH regarding the use of short tandem repeat systems, Vox Sang. 74 (1998) 61–63.

[15] A. Carracedo, W. Bär, P. Lincoln, W. Mayr, N. Morling, B. Olaisen, P. Schneider, B. Budowle, B. Brinkmann, P. Gill, M. Holland, G. Tully, M. Wilson, DNA Commission of the International Society for Forensic Genetics: guidelines for mitochondrial DNA typing, Forensic Sci. Int. 110 (2000) 79–85.

[16] P. Gill, C. Brenner, B. Brinkmann, B. Budowle, A. Carracedo, M.A. Jobling, P. de Knijff, M. Kayser, M. Krawczak, W.R. Mayr, N. Morling, B. Olaisen, V. Pascali, M. Prinz, L. Roewer, P.M. Schneider, A. Sajantila, C. Tyler-Smith, DNA Commission of the International Society of Forensic Genetics: recommendations on forensic analysis using Y-chromosome STRs, Int. J. Legal Med. 114 (2001) 305–309.

[17] EN ISO/IEC 17025: 1999 standard ‘General requirements for the competence of testing and calibration laboratories’, International Standardisation Organisation, Geneva, Switzerland, 1999.