| DNA Working Group: Quality Assurance Programme For DNA Laboratories | | | |
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# QUALITY ASSURANCE PROGRAMME

# FOR

# DNA LABORATORIES

# Contents:

## 1. INTRODUCTION

This programme describes a model of quality assurance as recommended by the ENFSI DNA WG. The programme is intended to set standards for the exchange of data between European member states when they use STR loci for the exchange of DNA profiles. This programme is not intended to replace or restrict other alternative quality assurance programmes that exist within countries of Europe which may be considered comparable to the guidelines provided here and would enable a laboratory to take part in the exchange of data. It further does not include validation requirements for entering profiles onto a national database. A further restriction of this programme is that it provides no guidance or comment on the use of other validated DNA test systems that exist and are used throughout Europe. Such systems are beyond the scope of this programme. This programme aims to help identify all aspects of quality which DNA testing laboratories should address when seeking accreditation according to ISO/IEC 17025 2005 or compliance with ENFSI DNA WG recommendations for the transfer and exchange of DNA data between laboratories.

## 2. STANDARDS

ISO/IEC 17025 2005 General Requirements for the Competency of Testing and Calibration Laboratories

## 3. REFERENCES

Quality Management and Quality Assurance - Vocabulary **ISO 8402: 1994**

Guidelines for Forensic Science Laboratories ILAC-G19:2002

European Council Resolution of 9th June 1997 on the exchange of DNA analysis results (97/C 193/02).

Council Decision 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime

Council Resolution of 30 November 2009 on the exchange of DNA analysis results 2009/C 296/01 ESS extension

Council framework Decision 2009/905/JHA of 30 November 2009 on Accreditation of forensic service providers carrying out laboratory activities

INTERPOL HANDBOOK ON DNA DATA EXCHANGE AND PRACTICE Recommendations from the Interpol DNA monitoring expert group – second edition 2009.

## 4. SCOPE

The programme describes the quality assurance requirements that a laboratory should follow to ensure the quality and integrity of the data and competency of the laboratory conducting forensic DNA analysis. Adherence to this programme, or a comparable one, is recommended for acceptance of data and its transfer and exchange between laboratories in Europe as laid down in the European Council 2008/616/JHA of 23 June 2008 on the implementation of Decision 2008/615/JHA on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime.

## 5. DEFINITIONS

### *Accreditation/Quality related definitions*

(a) Accreditation is the formal recognition that a laboratory is competent to carry out specific calibrations or tests.

(b) Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

(c) Vertical audit is an audit of every aspect of a process from beginning to end.

(d) Quality assurance: All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

(e) Quality manual is a document stating the quality policy, quality system and quality practices of an organisation.

(f) Quality system is the organisational structure, responsibilities, procedures, processes and resources for implementing quality management.

(g) Quality Management Review is a review of the quality system.

(h) Standard Operating Procedures SOPs are the specified methods, procedures or protocols.

(i) Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

(j) Reference material (certified or standard): A material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(k) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis.

***Personnel related definitions***

(a) Reporting Officer is an individual who conducts and/or directs the analysis of forensic casework samples, interprets data, reaches conclusions and reports these to a court of law in statement format and verbally as appropriate.

(b) Technical Manager/DNA Manager is an individual who manages the technical operations of the laboratory.

(c) Technician/Analyst is an individual who performs analytical techniques on evidence samples and/or performs DNA analysis on samples. Technicians do not interpret or reach conclusions on results or prepare final reports and their work is supervised.

*Any one scientist may fulfil one or more of the roles identified above*

(d) Laboratory support personnel/laboratory support are individual(s) who perform laboratory duties and do not analyse evidence samples.

***Technical/Analytical related definitions***

(a) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

(b) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

(c) Positive control consists of an aliquot of known DNA sample which ideally is heterozygote at all loci.

(d) Commercial test kit is a pre-assembled kit that allows the user to conduct a specific forensic DNA test.

(e) Crime stains are samples recovered from a crime scene or recovered from items related to an alleged offence.

(f) Reference/donor samples are biological samples whose identity or type is established.

(g) Competency testing is the assessment of an individual's ability to perform a specified technical activity.

(h) Proficiency testing is the assessment of a laboratory's ability to perform specific technical activities and includes the use of inter-laboratory comparisons to determine the performance of individual laboratories for specific tests or measurements in addition to monitoring laboratories' continuing performance.

## 6. MANAGEMENT REQUIREMENTS

### 6.1. ***Organisation and Management*** **-** (ref 17025 2005, 4.1-4.2)

6.1.1. The laboratory or the organisation of which it is part should be legally identifiable.

6.1.2. The organisation must have arrangements to ensure that its management and personnel are free from any undue internal and/or external pressures that may adversely affect the quality of their work.

6.1.3. The laboratory must:

(a) Define, with the aid of diagrams, the organisational and management structure of its place in any parent organisation, and the relations between management, technical operations, support services and the quality system

(b) Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests

(c) Identify objectives and responsibilities for all key roles

(d) Ensure that its managers and technical personnel are provided with the resources needed to ensure the required quality of laboratory operations

(e) Have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results

(f) Have policies and procedures which reinforce the need for impartiality and operational integrity

(g) Appoint a member of staff as quality manager (however named) who must have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and irrespective of other duties and responsibilities, must have defined responsibility and authority for ensuring compliance with the quality system at all times

### 6.2. ***Management system*** **-** (ref 17025 2005, 4.2)

6.2.1. The laboratory management must establish, implement and maintain a quality system appropriate to the scope of its activities including the type, range and volume of the testing it undertakes. The laboratory management must document its policies, systems, programmes, procedures and instructions, to the extent necessary to enable the laboratory to assure the quality of tests it carries out. This documentation must be readily available to all appropriate personnel involved in its implementation.

6.2.2 The laboratory management must define and document its policies and objectives to be achieved by implementing the quality system. The laboratory management must ensure that these policies and objectives are documented in a quality manual. The overall objectives must be set out in a quality policy statement in the quality manual stating the standard of performance to be maintained. The quality policy statement must be issued under the authority of the chief executive/senior officer/director. It should preferably be a concise statement and must include at least the following:

a) A statement of the laboratory management's' intentions with respect to the standard of service it will provide

b) The purpose of the quality system

c) A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarise themselves with the quality documentation and implement the policies and procedure in their work

d) The laboratory management's' commitment to good professional practice and quality of its testing calibration in servicing its customer/client

e) The laboratory management's' commitment to compliance with the agreed standard

f) The quality policy statement should include the requirement that tests and/or calibrations must always be carried out in accordance with stated standardised methods and clients' requirements

6.2.3 The quality manual must include or make reference to the supporting procedures including technical procedures. It must outline the structure of the documentation used in the quality system. The quality manual must be maintained up to date.

6.2.4 The quality manual must define the roles and responsibilities of technical management and the quality manager including their responsibility for ensuring compliance with the agreed standard.

6.2.5 The quality manual must also contain the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications.

6.2.6 The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

6.3. ***Internal Audits -*** (ref 17025 2005, 4.14)

6.3.1. The laboratory will conduct regular audits of all aspects of the DNA Quality System. The audits will be timetabled in a documented programme and include where appropriate:

(a) Quality assurance program

(b) Quality System

(c) Organisation and Personnel issues

(d) Marketing, Contract Review and Customer Complaints

(e) Procurement and Material Control

(f) Management of casework and other Services

(g) Scientific Methods and Protocols

(h) Equipment Calibration and Maintenance

(i) Accommodation and Security

(j) Finance and accounting

(k) Reporting the results

(l) Previous audits

6.3.2. The laboratory will retain all documentation pertaining to audits in accordance with laid down policy.

6.4. ***Corrective Action*** (ref 17025 2005, 4.11)

6.4.1. Whenever testing discrepancies are detected the laboratory will establish procedures for corrective action within defined timescales.

6.4.2. The laboratory will maintain documentation for the corrective action which should include details such as nature of discrepancy/complaint, control of non conforming testing, details of improvements and preventative actions.

6.5. ***Health and Safety -*** (ref 17025 2005, 1.5)

6.5.1. The laboratory will have a documented environmental health and safety program.

6.6. ***Subcontracting of Analytical Testing -*** (ref 17025 2005, 4.5)

6.6.1. The laboratory will ensure and be able to demonstrate that any sub-contractor meets the quality requirements as outlined in this document.

6.6.2. The laboratory will maintain a record of its investigation of the competence and compliance of its sub-contractor.

6.7. ***Management Review -*** (ref 17025 2005, 4.15)

6.7.1. The management of the laboratory with executive responsibility must periodically (for example once every 12 months) conduct a review of the laboratory's quality system and testing activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements. The review must take account of reports from managerial and supervisory personnel, the outcome of recent audits and corrective and preventative actions, assessments by external bodies, the results of interlaboratory comparisons or proficiency tests, any changes in the volume and type of the work undertaken, `feedback from clients, including complaints and other relevant factors, such as quality control factors, resources and staff training.

6.7.2. Findings from the management reviews and the actions that arise from them must be recorded. The management must ensure that those actions are discharged within an appropriate and agreed timescale.

## 7. *TECHNICAL REQUIREMENTS*

7.1. ***General -*** (ref 17025 2005, 5.1)

7.1.1. This section addresses the requirements a laboratory has to meet in order to be able to demonstrate that it is technically competent for DNA testing.

7.2. ***Personnel -*** (ref 17025 2005, 5.2)

7.2.1. The laboratory management must ensure that all personnel who perform any aspect of the testing procedures are competent.

7.2.2. The laboratory must have up to date job descriptions for all staff which include responsibilities, duties and skills.

7.2.3. The management of the laboratory must have a documented training programme for qualifying all technical laboratory personnel.

7.2.4. The management of the laboratory shall formulate the goals with respect to the education and the skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to present and anticipated tasks of the laboratory.

7.2.5. The laboratory must maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

7.3. ***Qualifications*** **-** (ref 17025 2005, 5.2.2)

7.3.1. Technical Manager/DNA managers/Reporting Officers should have a degree or an equivalent qualification in the specialist area. For those individuals who do not have academic qualifications then relevant equivalent experience is required.
All individuals who fulfil these roles must demonstrate competence.

7.3.2. Technicians/Analysts/Laboratory Support personnel must have either a technical qualification or equivalent to provide a basis for understanding forensic DNA testing and demonstrate competence.

7.4**.** ***Competency testing*** **-** (ref 17025 2005, 5.2.1 -.5.2.2)

7.4.1. The laboratory must ensure that the competence of its staff is regularly assessed for all relevant aspects of DNA testing, against documented criteria. (See *Concept Training Document*).

7.4.2. Each analyst will at the end of their training period undertake a competency assessment/test which has to be successfully completed before they can analyse casework samples. Thereafter the work of each analyst will be monitored to ensure continuing competence.

7.4.3. Reporting Officers should be assessed during and at the end of their training via competency exercises and thereafter audits and monitoring of casefiles will be undertaken.

7.5**.** ***Accommodation and environmental conditions*** **-** (ref 17025 2005, 5.3)

7.5.1. The laboratory will have a facility that is designed to provide adequate security and minimise the risk of contamination. (See *Contamination Prevention Guidelines*).

7.5.2. Access to the laboratory must be controlled and limited.

7.5.3. *A minimum of four separate designated work areas are required.*

7.5.3.1 Work area 1 for the general handling of samples and note writing. The examination of low template DNA samples should be undertaken in separated work areas

7.5.3.2 Work area 2 in which PCR set-up is undertaken. The analysis of crime stains and reference samples should be separated by time and/or space.

7.5.3.3 Work area 3 dedicated to PCR amplification and the handling of amplified DNA (post PCR area).

7.5.3.4 DNA extraction can be carried out in work area 1 or 2 (Pre-PCR areas).

7.5.3.5 Work area 4: the extraction of reference samples should be done in a separate area from crime scene samples.

7.5.4 The reason for work area 3 is that amplified DNA product should be generated, processed and maintained in a room(s) that are separate from the evidence examination (search and recovery), DNA extraction and PCR set-up areas.

7.5.5 Work areas 1 and 2 may be located in one laboratory provided time and/or space separate the analyses. However, the best practice is to have at least three separate designated areas.

7.5.6 The laboratory must have written procedures for environmental monitoring, cleaning and decontaminating facilities and equipment. (See *Contamination Prevention Guidelines*).

7.6. ***Analytical Testing and Calibration Methods -*** (ref 17025 2005, 5.4 – 5.8)

7.6.1. The laboratory must use validated methods and procedures.

7.6.2. Novel forensic DNA methodologies will undergo validation to ensure the reliability, robustness and reproducibility of the technique as appropriate and fit for purpose. Validation experiments should be designed to investigate the limits of the system and should include species and somatic specificity, environmental studies and mixture experiments. Internal validation should be done according to the *Recommended Minimum Criteria for the Validation of various aspects of the DNA Profiling Process*.

7.6.3. Population distribution data will be documented and available. Laboratories databases must be tested using statistical methods.

7.6.4. Samples submitted for DNA testing should be prepared following recommended PCR procedures as laid down in INTERPOL Recommendations for Collection, Packaging and Preservation of the Evidence for DNA Analysis.

7.6.5. All laboratory DNA analytical procedures must be agreed and documented. Protocols for searching of exhibits and pre-testing work should also be documented.

7.6.6. The laboratory will use reagents and equipment that are suitable for the forensic analysis

7.6.7. The laboratory will have a documented program to ensure that instruments and equipment are properly maintained and calibrated with written logs for maintenance/calibration records.

7.6.8. Where available and appropriate, standards traceable to national or international standards will be used for the calibration.

7.7. ***Technical guidelines for STR Profiling Systems -*** (ref 17025 2005, 5.4.1)

7.7.1. To ensure comparability a minimum of systems used for determining STR profiles for inclusion on a National DNA Database, must be based on the recommended ENFSI STR loci i.e. ESSOL, allele nomenclature and presentational format (See FORENSIC-SCI-INT;1997; V87 (3); June; P185-192; INT-J-LEG-MED;1997; V110 (4); August; P175-176; VOX-SANG;1998; V74; P61-63 and LEGAL-MED-ANN;2001; V3; December; P252-257).

7.7.2. All critical reagents and equipment should be validated according to an agreed documented procedure. See validation guidelines document

7.7.3. The conditions and equipment for which the system has been validated must be fully specified and followed. If a commercial kit is used then this may be found in the user's manual.

7.7.4. Significant/critical changes to the specified conditions and equipment affecting the compatibility of results should be shared/presented discussed and evaluated by the ENFSI DNA working group, properly validated and published for peer review (or, where that is not possible, provided for review by the ENFSI DNA working group), prior to being implemented. This will ensure compatibility of results and methodology. There could be exceptions to this if labs feel there is a conflict of interest, however appropriate validation and compatibility of results should still be undertaken.

7.7.5. The STR Profiling System - Minimum Standards

7.7.5.1. At least one allelic ladder per loading or injection batch must be run.

7.7.5.2. Detection systems should achieve 1 base pair separation at all STR loci over the read range.

7.7.5.3. An internal size standard must be run with each sample and the profile of the sample will only be accepted if each peak of the size standard has been correctly designated within the analysis range (2 smaller and 2 larger).

7.7.5.4. A reagent blank control (extraction negative) must be used routinely to confirm the validity of the extraction procedure. This is particularly useful and recommended for analysis of weak stains where it is likely that large amounts of extract will be taken through the amplification process.

7.7.5.5. An amplification blank control (PCR negative control) must be used routinely to confirm the validity of the PCR.

7.7.5.6. At least one PCR positive control per loading or injection batch must be run on each gel. Ideally the positive control should be heterozygote for all the loci detected. This is used to check the validity of the PCR.

7.7.6. *Designation of alleles*

7.7.6.1. The designation of alleles and rare alleles must adhere to recommended guidelines, including National and International DNA database requirements. (See Appendix *number 3 for an example of such guidelines on the ENFSI Website*)

7.7.6.2. Each allele must be designated via two independent stages when done manually. When using expert systems only one stage is enough as long as the quality requirements are fulfilled.

7.7.6.3. If there is any doubt designating an allele then a wild card value should be assigned or the sample re-processed.

7.7.7. *Profile acceptance criteria*

The following are required for profiles to be deemed acceptable for recording on a National DNA database:

- Process controls (allelic ladder, positive and negative controls, etc.) are valid within the batch
- Control measures for contamination monitoring for each batch is clear
- Profile must fulfil national/international database requirements

7.7.8. It may be appropriate to repeat the sample if after analysis of the data the laboratory based quality criteria are not met.

## 7.8. *Chain of Evidence/Custody and Evidence Control* - (ref 17025 2005, 5.8)

7.8.1. The laboratory will have a documented evidence control system to ensure the integrity of physical evidence.

7.8.2. This system will ensure that:

7.8.2.1 Evidence is marked for identification.

7.8.2.2 Chain of evidence/custody for all evidence is maintained.

7.8.2.3 The laboratory follows documented procedures that minimise loss, contamination, and/or deleterious change of evidence.

7.8.2.4 The laboratory has secure areas for evidence storage.

7.8.3. Where possible, the laboratory will retain a portion of the evidence sample, or extract, for additional testing.

Forensic samples will be divided into two or more parts at the earliest practicable stage and the unused parts retained to permit additional tests, except those cases where because of the small quantity of the staining this is likely to compromise the quality of the results produced at the first analysis. The used and saved portion (either a piece of the stain or the item itself) should be stored and handled separately. Any additional tests should be performed independently of the first.

7.8.4. Retained evidence sample/extract(s) will be stored in a specified manner that can be shown to minimise degradation.

## 7.9. *Proficiency Testing* - (ref 17025 2005, 5.9)

7.9.1. DNA laboratories must participate regularly in a proficiency testing programme covered by the scope of the laboratory's accreditation. The use of national or ENFSI approved schemes and providers accredited to ISO 17043 are recommended.

7.9.2. The laboratory must maintain the following records for proficiency tests:

(a) The test set identifier

(b) Identity of the analyst(s)

(c) Date of analysis and completion

(d) Copies of all data sheets and notes supporting the conclusions

(e) The proficiency test results

(f) Any discrepancies noted

(g) Corrective actions taken

7.10. ***Reporting the Results -*** (ref 17025 2005, 5.10)

7.10.1. The laboratory will have written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory report.

7.10.2. The laboratory will maintain, in a case record/file, all documentation generated and related to case analyses.

7.10.3. When available and appropriate reports according to written guidelines should include the following elements:

(a) Case identifier

(b) Details about the receipt of the items

(c) Information given about the case or scenario provided

(d) Purpose of the work undertaken

(e) Laboratory examination

(g) Results with details tabulated separately

(h) Interpretation

(i) Appendix containing a description of DNA technology used, (where appropriate)

(k) A signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report.

7.10.4. The laboratory will have written procedures for the release of case report information.

7.10.5. The laboratory will have written general guidelines for the interpretation of data, including mixed body fluid stains and samples with a limited quantity of DNA, where stochastic effects are pronounced.

7.10.6. Laboratories should report results following agreed interpretation, presentation, nomenclature, and formatted procedures.