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SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF DNA PROFILING FOR FORENSIC SCIENCE TESTING LABORATORIES

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Table of Contents		Page
1.	Introduction & Scope	2
2.	Normative References	2
3.	Definition	2
4.	Management Requirements	4
4.14	Internal Audits	4
5.	Technical Requirements	4
5.1	General	4
5.2	Personnel	4
5.3	Accommodation and Environmental conditions	5
5.4	Test and method validation	6
5.5	Equipment	7
5.6	Measurement traceability	7
5.7	Sampling	7
5.8	Handling of test and calibration items	7
5.9	Assurance the Quality of Test and Calibration Result	7
5.10	Reporting of Results	8

ACCREDITATION OF DNA PROFILING FOR FORENSIC SCIENCE TESTING LABORATORIES

1. Introduction and Scope

The purpose of this document is to specify specific technical requirements for Accreditation of DNA Profiling for Forensic Science Testing Laboratories for the following scope:

- i. forensic DNA profiling
- ii. paternity testing using DNA method

This document shall be read in conjunction with standard MS ISO/IEC 17025:2005 and SAMM criteria and requirements. The clause numbers in this document correspond to those in the standard.

2. Normative references

- i) MS ISO/IEC 17025 : 2005 – General Requirements for the Competence of Testing and Calibration Laboratories
- ii) SC 1.1 – Specific Criteria for Accreditation of Forensic Science Testing

3. Definitions

- a. Administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies, improvement and corrective action.
- b. Review is an evaluation of documentation to check for consistency, accuracy, and completeness.
- c. Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. This review is conducted by another qualified individual.
- d. Laboratory is a facility where forensic DNA profiling is performed.
- e. Analytical procedure is an orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.
- f. Commercial kits are pre-assembled kit that allows the user to conduct a specific DNA identification test.
- g. Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA analysis.
- h. Secure area is a locked space (e.g., cabinet, vault, room) with access restricted to authorized personnel.

- i. Polymerase chain reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles that consist of : (i) denaturation of the template,(ii)annealing of primers to complementary sequences at an empirically determined temperature, and (iii) extension of the bound primers by a DNA polymerase.
- j. Audit is an assessment use to evaluate, confirm, or verify activity related to quality.
- k. Calibration is the set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material and the corresponding known values of a measurement.
- l. Technical manager (or equivalent position or title as designated by the laboratory director) is the individual who is accountable for the technical operations of the laboratory.
- m. Technical analyst (or equivalent role, position, or title as designated by the laboratory director) conducts and/or directs the analysis of samples, interprets data, and reaches conclusions.
- n. Technical personnel are person who qualified and assigned by the laboratory director to carry out Forensic DNA profiling.
- o. Forensic DNA profiling is the identification and evaluation of biological matters using DNA technologies.
- p. Proficiency testing is a quality assurance measure used to monitor quality performance of a laboratory and/or individual. Proficiency tests should be classified as:
 - i)Internal proficiency test is one prepared and administered by the laboratory or;
 - ii)External proficiency test, which should be open or blind, is one that is obtained from a second agency.
- q. Technical competency is a test that measures proficiency in both technical skill and knowledge.
- r. Quality assurance includes the systematic actions necessary to demonstrate that a produce or service meets specified requirements for quality.
- s. Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.
- t. Credit hour is a unit of measure representing the equivalent of an hour (60 minutes) of instruction per week over the entire term. It is applied toward the total number of credit hours needed for completing the requirements of a formal award.

4. Management Requirements

Clause 4.1- 4.13 and 4.15

As in the MS ISO/IEC 17025.

4.14 Internal Audits

- 4.14.1 An internal audit of DNA laboratory shall be carried out at least once a year. At least one member of the auditing team shall be a qualified analyst in the forensic DNA profiling technology (e.g. Short Tandem Repeats (STRs) or mitochondrial DNA (mtDNA)).

5 Technical Requirements

5.1 General

The forensic DNA profiling laboratory shall have sufficient personnel having the necessary training, technical knowledge and experience for the assigned functions. The laboratory shall have written job descriptions for all personnel to include responsibilities, duties, and skills.

5.2 Personnel

- 5.2.1 The technical manager of the laboratory shall meet the following degree/educational requirements:

- i) A graduate in degree of Forensic Science, Biology, Chemistry and/or any relevant discipline.
- ii) Shall have a minimum of one year forensic DNA laboratory experience.
- iii) A minimum of 12 credit hours including a combination of graduate and undergraduate course work or classes covering the subject areas of biochemistry, genetics, molecular biology and statistics or equivalent certified training and working experiences in relevant above subject areas.

- 5.2.2 The technical analyst shall meet the following degree/educational requirements:

- i) A graduate in degree of Forensic Science, Biology Chemistry and/or any relevant discipline.
- ii) A minimum of six months forensic DNA laboratory experience.
- iii) A minimum of 12 credit hours including a combination of graduate and

undergraduate course work or classes covering the subject areas of biochemistry, genetics, molecular biology and statistics or equivalent certified training and working experiences in relevant above subject areas.

- 5.2.3 The laboratory shall have a documented program to ensure the technical competency are maintained through continuing education.

5.3 Accommodation and environmental conditions

5.3.1 Security

- 5.3.1.1 Clearly written and well-understood procedures shall exist for laboratory security.
- 5.3.1.2 The laboratory's security system shall control access and limit entry to the operational areas.
- 5.3.1.3 All exterior entrance/exit points to the facility shall be secured and controlled in a manner to prevent access by unauthorized personnel.
- 5.3.1.4 Internal controlled areas shall limit access to only authorized personnel.
- 5.3.1.5 The distribution of all keys and combinations shall be limited to appropriate laboratory personnel as designated by laboratory management. The distribution system shall be current, accurate, clearly documented, and available for review.

5.3.2 Test System facilities

- 5.3.2.1 The laboratory's approach to sample processing shall demonstrate a separation in time or physical space for each activity.
- 5.3.2.2 When robotic workstations are used to carry out DNA extractions through PCR setup on casework samples, a single room should be used.
- 5.3.2.3 The laboratory shall have written procedures for monitoring contamination, cleaning, and decontaminating facilities and equipment.
- 5.3.2.4 The laboratory should have sufficient storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against contamination and/or deterioration.
- 5.3.2.5 The laboratory should ensure a comfortable and safe working environment

5.4 Test methods and Method Validation

5.4.1 Test Methods

5.4.1.1 The laboratory shall have and follow written analytical procedures approved by designated personnel.

5.4.1.2 The laboratory shall have written procedures for documenting commercial suppliers and for formulating reagents.

5.4.1.3 The laboratory shall identify the reagents, commercial kits and equipments critical to the analytical processes used, and verify prior to their use on evidence samples.

5.4.1.4 The laboratory shall review their procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available standard reference material (SRM).

5.4.2 Validation

5.4.2.1 The laboratory shall use methods and procedures for forensic DNA profiling that have been validated prior to casework implementation.

5.4.2.2 The laboratory shall have access to a population database that is documented and available for use in population statistics. The database information should include allele and frequency distributions for the locus or loci obtained from relevant populations.

5.4.2.3 The laboratory shall have completed and documented the internal validation studies. The internal validation studies conducted by the forensic DNA profiling laboratory should be sufficient to document the reliability of the technology as practiced by that laboratory. Summaries shall be written for all internal validation studies and approved by the technical manager/leader.

5.4.2.4 Prior to implementing a new forensic DNA profiling procedure or an existing forensic DNA profiling procedure validated by another laboratory, the forensic DNA profiling laboratory must first demonstrate the reliability of the procedure internally.

5.4.2.5 For laboratory systems that consist of more than one laboratory, each of the laboratories shall complete and maintain performance-based validations (e.g.: sensitivity and precision), while basic validation studies may be shared among all locations in a laboratory system.

5.4.2.6 Each new instrument or performance-based software change (including upgrades) requires a performance check. A performance check is an evaluation

of a validated procedure existing in the laboratory system to ensure that it conforms to specifications and may include such studies as reproducibility and sensitivity.

5.5 Equipment

As in MS ISO/IEC 17025

5.6 Measurement traceability

As in MS ISO/IEC 17025

5.7 Sampling

As in MS ISO/IEC 17025

5.8 Handling of test items

5.8.1 Evidence and Sample Control

5.8.1.1 The laboratory shall maintain a chain of custody for all evidence. This record should provide a comprehensive, documented history for each evidence transfer over which the laboratory has control.

5.8.1.2 The laboratory shall ensure that evidence stored under its custody is properly sealed, secured and protected from loss and contamination.

5.8.1.3 Secure area and arrangements for temporary or short-term storage shall exist in the laboratory.

5.8.1.4 The laboratory shall have procedure for the retention and disposal of samples.

5.9 Assuring the quality of test results

5.9.1 Proficiency Testing

5.9.1.1 Technical personnel who participate in forensic DNA profiling shall undergo one proficiency testing program per year (as listed in the SAMM Policy 4).

5.9.1.2 Technical personnel shall participate in each aspect of the DNA process in which they perform Forensic DNA profiling over the course of a year.

5.9.1.3 Newly technical personnel who has successfully completed the internal induction training shall enter into the external proficiency testing program within six months.

5.9.1.4 The laboratory shall have and use a documented program for evaluating proficiency testing data.

5.9.1.5 The laboratory shall have and follow written procedures as well as maintain the documentation for taking corrective action whenever proficiency testing discrepancies and/or casework errors are detected.

5.10 Reports

- 5.10.1 The laboratory shall have written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports.
- 5.10.2 The laboratory shall maintain all documentation generated by examiners related to case analyses.
- 5.10.3 The laboratory shall generate sufficient documentation for each technical analysis to support the reported conclusions such that in the absence of the technical analyst who performed the analysis, another qualified individual could evaluate and interpret the resulting data.
- 5.10.4 The laboratory report shall include the following criteria:
- (a) Case identifier
 - (b) Description of evidence examined
 - (c) Method used
 - (d) Results and conclusions
 - (e) Date issued
 - (f) Disposition of evidence
 - (g) Signature and title of the technical analyst
- 5.10.5 The laboratory shall have written procedures for the release of case report information.
- 5.10.6 The laboratory shall have written procedures defining the elements associated with both administrative and technical reviews to ensure conclusions and supporting data are reasonable and in the constraints of scientific knowledge.
- 5.10.7 The laboratory shall define the qualifications and responsibilities of the administrative reviewer and technical reviewer. The administrative reviewer is not required to be a current or former qualified DNA technical analyst.
- 5.10.8 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers.
- 5.10.9 The laboratory shall have written procedures to monitor and review of the court testimony of each technical personnel.

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